PATENT COOPERATION TREATY

CORRECTED VERSION

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

SPRUSON & FERGUSON
GPO Box 3898
SYDNEY NSW 2001

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing (day/month/year) 21 AUG 2001

Applicant's or agent's file reference
507717c

IMPORTANT NOTIFICATION

International Application No.	International Filing Date	Priority Date
PCT/AU00/00654	9 June 2000	10 June 1999

Applicant

SUNSHINE HEART COMPANY PTY LTD et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide

Name and mailing address of the IPEA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	ROSEMARY LONGSTAFF Telephone No. (02) 6283 2637

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CORRECTED VERSION

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY CORRECTED VERSION

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 507717c	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. **PCT/AU00/00654**	International Filing Date *(day/month/year)* 9 June 2000	Priority Date *(day/month/year)* 10 June 1999

International Patent Classification (IPC) or national classification and IPC

Int. Cl. [7] A61M 1/12

Applicant

SUNSHINE HEART COMPANY PTY LTD et al

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of **5** sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of **26** sheet(s).

3. This report contains indications relating to the following items:

I	[X]	Basis of the report
II	[ ]	Priority
III	[ ]	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	[X]	Lack of unity of invention
V	[X]	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	[ ]	Certain documents cited
VII	[ ]	Certain defects in the international application
VIII	[X]	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
28 December 2000	1 August 2001
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **ROSEMARY LONGSTAFF** Telephone No. (02) 6283 2637

CORRECTED VERSION

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU00/00654

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed.

☒ the description, pages , as originally filed,
pages **1-3, 5, 7-18,** received on **19 April 2001** with the letter of **18 April 2001,**
pages **4, 6,** received on **29 June 2001** with the letter of **28 June 2001**

☒ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages **19, 21-22, 24-26,** received on **19 April 2001** with the letter of **18 April 2001,**
pages **20, 23,** received on **29 June 2001** with the letter of **28 June 2001**

☒ the drawings, pages **1-10,** as originally filed,
pages , filed with the demand,
pages , received on with the letter of

☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

CORRECTED VERSION

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU00/00654

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:

The only feature common to all of the claims is an aortic compression means. However this common feature is generic in the art. Consequently the common feature does not constitute "a special technical feature" within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art. Since there exists no other common feature which can be considered as a special technical feature within the meaning of PCT Rule 13.2, second sentence, no technical relationship within the meaning of PCT Rule 13 between the different inventions can be seen. Consequently it appears that a posteriori, the claims do not satisfy the requirement of unity of invention.

In the specification, there are four inventions, as follows:

1. Claims 1-19 and 23-56 relate to an aortic compression means so shaped and dimensioned that it is adapted, when actuated, to compress the ascending aorta of a patient
2. Claims 20 and 21 relate to an inflatable cuff including two free ends which are adapted to overlap when the cuff is placed around the aorta.
3. Claim 22 relates to an aortic compression means wherein a pump means and a fluid reservoir are provided in a fluid filled, substantially air-tight housing.
4. Claim 57 relates to an aortic compression means including a fluid reservoir with a flexible erior exterior surface which is adapted to be placed adjacent a lung in the patient's chest cavity.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☒ all parts.

☐ the parts relating to claims Nos.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU00/00654

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-59	YES
	Claims	NO
Inventive step (IS)	Claims 1-59	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-59	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

All claims are novel and involve an inventive step over the prior art. None of the cited documents, alone or in combination, disclose, or fairly suggest, all of the features of claims 1-59

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU00/00654

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The invention is not clearly described. The "Summary of the Invention" gives thirteen "aspects" of the invention, with the only feature common to all these aspects being an aortic compression means. Such a means is well known in the art of heart assist devices.

CLAIMS

1. A heart assist device adapted for implantation into a patient, the device including:

a) an aortic compression means is so shaped and dimensioned that it is adapted, when actuated, to compress the ascending aorta of a patient;

b) a fluid reservoir; and

c) an electrically powered pump means adapted to pump a fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means at least partly in counterpulsation with the patient's heart,

the fluid reservoir and the pump means are so shaped, dimensioned and interconnected that they are adapted to be wholly positioned within the right chest cavity of the patient.

2. A device as claimed in claim 1, wherein the fluid is a liquid.

3. A device as claimed in claim 2, wherein the liquid is water or saline.

4. A device as claimed in any one of the preceding claims, wherein the aortic compression means is curved along its length so as to substantially replicate the curve of the aorta adjacent to the aortic compression means.

5. A device as claimed in any one of the preceding claims, wherein the aortic compression means includes an elastic inflatable cuff adapted to at least partly encircle the aorta.

6. A device as claimed in claim 5, wherein the cuff is adapted to completely encircle the aorta.

7. A device as claimed in claim in claim 5 or 6, wherein the cuff is substantially C-shaped and includes two free ends that are adapted to overlap when the cuff is placed around the aorta.

8. A device as claimed in claim 7, wherein one of the free ends includes an elongated tongue adapted for suturing in an overlapping relationship to the other end to retain the device adjacent the aorta.

9. A device as claimed in any one of claims 5 to 8, wherein the cuff is a snug fit around the aorta of the patient.

10. A device as claimed in any one of the preceding claims, wherein the pump means and the fluid reservoir are provided in a fluid-filled substantially air-tight housing.

20. A heart assist device adapted for implantation into a patient, the device including:

a) an aortic compression means which includes an inflatable cuff and is so shaped and dimensioned that it is adapted to encircle and, when actuated, compress the aorta of a patient, the cuff being substantially C-shaped and including two free ends that are adapted to overlap when the cuff is placed around the aorta ;

b) a fluid reservoir; and

c) pump means adapted to pump a fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means at least partly in counterpulsation with the patient's heart,

the fluid reservoir and the pump means are so shaped, dimensioned and interconnected that they are adapted to be wholly positioned within the chest cavity of the patient.

21. A heart assist device adapted for implantation into a patient, the device including:

a) an aortic compression means which includes an inflatable cuff and is so shaped and dimensioned that it is adapted to substantially encircle and, when actuated, compress the aorta of a patient, the cuff having two free ends, one of which includes an elongate tongue adapted for suturing or other connection in an overlapping relationship to the other end to retain the cuff in place around the aorta ;

b) a fluid reservoir; and

c) pump means adapted to pump a fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means at least partly in counterpulsation with the patient's heart,

the fluid reservoir and the pump means are so shaped, dimensioned and interconnected that they are adapted to be wholly positioned within the chest cavity of the patient.

22. A heart assist device adapted for implantation into a patient, the device including:

a) an aortic compression means which, when actuated, compress the aorta of a patient;

b) a fluid reservoir; and

c) pump means adapted to pump a fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means at least partly in counterpulsation with the patient's heart,

the fluid reservoir and the pump means are so shaped, dimensioned and interconnected that they are adapted to be wholly positioned within the chest cavity of the patient and the pump means and the fluid reservoir are provided in a fluid filled substantially air-tight housing.

23. A heart assist device adapted for implantation into a patient, the device including:

a) an aortic compression means adapted, when actuated, to compress the ascending aorta of a patient;

b) a liquid reservoir;

c) a pump means adapted to pump a liquid from the liquid reservoir to the aortic compression means so as to actuate the compression means, the liquid reservoir and the aortic compression means being adapted to be positioned in close juxtaposition with one another within the chest cavity of the patient, and

d) means to sense the pressure in the liquid in the absence of aortic compression and alter the sensed pressure to a predetermined pressure .

24. A device as claimed in claim 23, wherein the distance between the liquid reservoir and the aortic compression means is no more than 6 cm.

25. A device as claimed in claim 19, 20, 21 or 22, further including a liquid conduit between the liquid reservoir and the aortic compression device which has minimum cross sectional area of at least 1 sq cm.

26. A device as claimed in any one of claims 23 to 25, further including a pressure compliance means.

27. A device as claimed in claim 26, wherein the liquid reservoir, the pump means and the pressure compliance means are provided in an air-tight housing.

28. A device as claimed in claim 27, wherein the housing is fluid-filled and the liquid reservoir is a portion of the interior of the housing.

29. A device as claimed in claim 27 or 28, wherein the pressure compliance means is a flexible portion of the housing adjacent the liquid reservoir.

30. A device as claimed in claim 29, wherein the flexible portion is adapted for positioning in juxtaposition with the lung of the patient.

wherein the cuff is substantially C-shaped and includes two free ends that are adapted to overlap when the cuff is placed around the aorta.

39. An aortic compression means for use in a heart assist device, the aortic compression means including:

a) an elastic inflatable cuff adapted to be placed about the ascending aorta of a patient; and

b) a flexible, substantially inelastic, sheath adapted to extend around the cuff and at least assist in retaining it in position on the aorta,

wherein the cuff is substantially C-shaped and includes two free ends, one of the free ends includes an elongated tongue adapted for suturing or otherwise connected in an overlapping relationship to the other end to retain the device adjacent the aorta.

40. A device as claimed in claim 37, 38 or 39, wherein the cuff is adapted to at least partially encircle the aorta.

41. A device as claimed in claim 40, wherein the cuff is adapted to completely encircle the aorta of the patient.

42. A device as claimed in claim 37 or 39, wherein the cuff is substantially C-shaped and includes two free ends that are adapted to overlap when the cuff is placed around the aorta.

43. A device as claimed in claim 37 or 38, wherein one of the free ends includes an elongated tongue adapted for suturing in an overlapping relationship to the other end to retain the device adjacent the aorta.

44. A device as claimed in any one of claims 37 to 43, wherein the cuff is a snug fit around the aorta of the patient.

45. A means as claimed in any one of claims 37 to 44, wherein the sheath is a snug fit around the cuff.

46. A device as claimed in any one of claims 37 to 45, wherein the cuff has a single inlet/outlet port.

47. A device as claimed in claim 46, wherein the sheath has an opening complimentary to the cuff inlet/outlet port.

48. A device as claimed in claim 37 to 47, wherein the cuff is inflatable to an enlarged pressurised configuration to compressing the aorta and relaxes to a static configuration to relax the aorta.

49. A heart assist device including:

a) an aortic compression means adapted by its shape and dimensions to be placed around the ascending aorta of a patient; and

b) mechanical or electrical actuation means to periodically actuate the aortic compression means in at least partial counterpulsation with the heart,

wherein the aortic compression means and the actuation means are placed wholly within the right chest cavity of the patient.

50. A device as claimed in claim 49, wherein the aortic compression means and the actuation means are adapted to be connected in close juxtaposition within the right chest cavity of a patient.

51. A device as claimed in claim 49 or 50, wherein the aortic compression means is inflatable to compress the aorta and the actuation means includes a pump means adapted to pump fluid into the aortic compression means to inflate same.

52. A device as claimed in claim 51, wherein the actuation means further includes a fluid reservoir and a pressure compensation means.

53. A device as claimed in claim 52, wherein the pump means, fluid reservoir and the pressure compensation means are contained in a fluid-filled air-tight housing.

54. A device as claimed in any one of claims 49 to 53, wherein the pump means is an impeller adapted to drive fluid from the fluid reservoir and the aortic compression means.

55. A device as claimed in any one of claims 51 to 53, wherein the pump means is a fluid-filled sac adapted to be compressed to drive fluid from the sac to the aortic compression means.

56. A device as claimed in any one of claims 51 to 55, wherein the aortic compression means is an inflatable cuff adapted for positioning about the aorta of the patient.

57. A heart assist device adapted for implantation wholly into the chest cavity of a patient, the device including:

a) an aortic compression means adapted, when actuated, to compress an aorta of a patient;

b) a housing with an exterior surface;

c) a fluid reservoir in the housing, the fluid reservoir having a flexible exterior surface forming part of the housing exterior surface; and

d) a pump means adapted to pump a fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means at least partly in counterpulsation with the patient's heart,

wherein the fluid reservoir flexible exterior surface is adapted to contract during aortic compression and expand in the absence of aortic compression and is further adapted to be positioned substantially adjacent a lung in the patient's chest cavity.

58. A device as claimed in claim 57, wherein the bodily cavity is the thoracic cavity and the organ is the lung.

59. A heart assist device as claimed in any one of claims 1 to 36, or 49 to 58 or an aortic compression device as claimed in any one of claims 37 to 48 when placed in a human or other animal .

11. A device as claimed in claim 10, further including a pressure compliance means.

12. A device as claimed in claim 11, wherein the pressure compliance means forms part of the housing.

13. A device as claimed in claim 12, wherein the pressure compliance means is a substantially rigid portion of the housing downstream of the pump means, the portion being of sufficient rigidity so as to not deform inwardly during aortic compression nor deform outwardly in the absence of aortic compression.

14. A device as claimed in claim 12, wherein the pressure compliance means is a substantially flexible portion of the housing downstream of the pump means, the portion being of sufficient flexibility so as to deform inwardly during aortic compression and deform outwardly in the absence of aortic compression

15. A device as claimed in claim 14, wherein the flexible portion is adapted to be positioned in juxtaposition with a lung of the patient and deform outwardly to slightly compress the lung in the absence of aortic compression.

16. A device as claimed in any one of claims 5 to 15, wherein the cuff has a single inlet/outlet port.

17. A device as claimed in claim 16, wherein the port has a diffuser therein.

18. A device as claimed in claim 16 or 17, wherein the housing has an inlet/outlet port opening in fluid communication with the cuff inlet/outlet port.

19. A heart assist device adapted for implantation into a patient, the device including:

a) an aortic compression means which is curved along its length so as to substantially replicate the curve of the ascending aorta adjacent to the aortic compression means and is so shaped and dimensioned that it is adapted, when actuated, to compress the aorta of a patient;

b) a fluid reservoir; and

c) pump means adapted to pump a fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means at least partly in counterpulsation with the patient's heart,

the fluid reservoir and the pump means are so shaped, dimensioned and interconnected that they are adapted to be wholly positioned within the chest cavity of the patient.

31. A device as claimed in any one of the claims 19 to 30, wherein the pump means is adapted for active compression of the aortic compression means and active decompression of the aortic compression means.

32. A device as claimed in any one of claims 19 to 30, wherein the pump means is adapted for active compression of the aortic compression means and passive decompression of the aortic compression means.

33. A device as claimed in any one of claims 19 to 32, further including a liquid pressure adjustment means between the aortic compression means and the liquid reservoir and in fluid communication with the aortic compression means and the liquid reservoir.

34. A device as claimed in claim 33, wherein the liquid pressure adjustment means is a remote reservoir positioned near the patient's skin that is adapted for the receiving or the removal of liquid therein via a needle though the skin.

35. A device as claimed in claim 34, wherein the liquid pressure adjustment means is a remote reservoir positioned in the chest cavity that is adapted for the receiving or the removal of liquid therein via a transcutaneous tube connected thereto.

36. A device as claimed in claim 19, 20, 21 or 22, further including a means to sense the pressure in the liquid pressure adjustment means in the absence of aortic compression and alter the sensed pressure to a predetermined pressure.

37. An aortic compression means for use in a heart assist device, the aortic compression means including:

a) an elastic inflatable cuff adapted to be placed about the ascending aorta of a patient; and

b) a flexible, substantially inelastic, sheath adapted to extend around the cuff and at least assist in retaining it in position on the aorta,

wherein the aortic compression means is curved along its length so as to substantially replicate the curve of the ascending aorta adjacent to the aortic compression means.

38. An aortic compression means for use in a heart assist device, the aortic compression means including:

a) an elastic inflatable cuff adapted to be placed about the ascending aorta of a patient; and

b) a flexible, substantially inelastic, sheath adapted to extend around the cuff and at least assist in retaining it in position on the aorta,

HEART ASSIST DEVICES, SYSTEMS AND METHODS

FIELD OF THE INVENTION

The present invention relates to heart assist devices, systems and methods.

BACKGROUND OF THE INVENTION

Currently the only real options for improvement of end-stage heart failure are medical therapy, left ventricular assist devices (LVADs) and transplantation. ACE (Angiotensin Converting Enzyme) inhibitors unload the heart and prolong survival. LVADs pump blood and significantly improve life style and survival, but are complicated to implant, maintain and remove, with relatively high complications relating to bleeding, infection, thromboembolism, and device malfunction.

The transplant rate has stabilised at approximately 2,300 per year in the USA, being limited by organ availability. Transplantation achieves a 75% five year survival rate and a 65% ten year survival rate with significant improvements in functional class.

The number of people awaiting heart transplantation is steadily increasing and they are a sicker group, with increasing numbers requiring hospitalisation, intravenous ionotropes, short-term percutaneous trans-femoral intra-aortic balloon pumping and/or LVAD implantation.

The Institute of Medicine has estimated that by the year 2010, up to 70,000 patients will be candidates for permanent mechanical circulatory support systems.

Over the last ten years, LVADs have been well proven to save lives, acting as bridges to transplantation for critically ill patients. Recently, LVADs have been considered as alternatives to transplantation, and very recently, have been explanted in a few patients who have shown recovery. This latest realisation is starting to gather a lot of interest as researchers focus on recovery of the failing heart. LVADs totally unload the left ventricle and many believe that the heart will then recover. Moreover there is evidence beyond the few patients in whom devices have been removed that there is reversal in markers of heart failure. On the other hand, others have described an increase in myocardial fibrosis which raises a question of whether the heart is being unloaded too much.

The intra-aortic balloon pump (IABP) was first proposed in the 1960s as a method of partial support for the acutely failing heart, for example, after heart surgery or heart attack. It was built as a long thin catheter [10-14 Fr] with an elongated balloon at its tip [volume 30-40 ml]. The balloon was inserted via the femoral artery and inflated and

deflated in counter-pulsation with the heart beat. Inflation in diastole causes a diastolic pressure augmentation and increases coronary artery blood flow and deflating in systole (triggered by the R wave of the ECG) reduces the afterload, or the pressure head against which the left ventricle has to eject blood. Early investigators determined that the best and most efficient balloon position was closest to the heart, i.e., in the ascending aorta. However, in recent times, the balloon is positioned via the femoral artery in the descending aorta for short term (1-10 days) use. There is substantial proof beyond doubt that counterpulsation works very well in the short-term to assist hearts to recover when drugs (ionotropes etc.) are insufficient or inappropriate to support the cardiovascular system.

Intra-aortic balloon heart pumps operating in counterpulsation assist the heart function. When inflated, the balloon propels blood peripherally from within the aorta to improve blood circulation in the patient. Moreover, more blood is forced into the coronary arteries to help nourish and strengthen the heart muscle. However, the balloon comes into direct contact with the blood flowing into the aorta, which can cause damage to the blood cells and there is a risk of thromboembolism. In addition, current intra-aortic balloon pump systems are inflated by means of a tube passing through the body, the tube connecting the balloon to an external compressor. The opening for the tube to enter the body provides a possible site of infection or other injury. The tube is typically inserted into a groin vessel, the femoral artery, and there is a high risk of associated leg complications. Further, the patient is bedridden and cannot mobilize. Additionally, the use of a gas to inflate the balloon is not an entirely safe operation since any leakage of gas from the balloon into the blood stream could cause an air embolus.

Aortic compression (periaortic diastolic compression) has been described as a means to increase coronary blood flow. For example, US Patent No. 4,583,523 describes an implantable heart assist device including an elongated assembly extending transversely between the ribs of a patient from the rib cage to the aorta of the heart to be assisted. The assembly includes an aorta compressing device at the front end and a mounting device at the rear end thereof to support the device from the ribs of the patient. A motive device actuates and deactivates the compressing device alternatively to help pump blood through the aorta in a counterpulsation mode of operation. Although this device has advantages for many applications, it does require relatively complicated surgery to implant/explant the device, particularly in regard to the need to mount the device, including its motive means, to the ribs of the patient. Moreover the mounting arrangement and motive means

of the device have to be positioned outside the rib cage, making the presence of the device more noticeable to the patient. There is also substantial risk of infection with the device coming through the skin. Furthermore, because the device is attached/mounted to the ribs, there may be shear stresses on the aorta as the rib cage moves with inspiration/expiration. These stresses may cause untoward damage of the aorta.

US Patent No. 4,979,936 discloses an autologous biologic pump in the form of an apparatus using skeletal muscle formed into a pouch which then surrounds a collapsible, shape-retaining bladder. The bladder is connected to a second bladder enclosed in a sheath around a portion of the aorta. The bladders are filled with a fluid such that when the skeletal muscle contracts in response to an electrical stimulation, the fluid is forced from the first bladder into the second bladder sheathed around the aorta, expanding that second bladder and forcing the aorta to compress. Although this approach may be useful in some circumstances, it is doubtful that it is suitable for long term in that the muscle function would probably degrade over time. Furthermore, the muscle has to be "trained" for many weeks before the device can be relied on to assist blood circulation.

WO 99/04833 discloses a cardiac ventricle aid device which is implanted in the abdominal cavity with an aorta sleeve tube placed on, or inserted in, the descending aorta. A disadvantage of the disclosed device is it has a separate actuator and compliance chamber and its implantation is thus complicated. Another disadvantage is it is difficult to securely mount the device components to a structure in the abdominal cavity that is capable of supporting its weight. A further disadvantage is a number of vertebral arteries stem from the descending aorta which can be damaged during the implantation of the device.

It would be desirable to have a heart assist device that could be quickly and totally implanted in a relatively easy manner and with minimum trauma to the patient and to allow ambulation with low risk of complications. Also desirable would be a heart assist device that allows partial unloading of the heart longterm, augmenting the cardiac output of the native heart, and possibly allowing substantial recovery of the heart so that the device could be weaned. Moreover, it would be desirable for such a device to have no blood contacting surfaces, and not require cardiopulmonary bypass to implant the device. In a small proportion of patients however there will exist aortic disease making a periaortic device unsuitable. In these patients it would be desirable to be able to apply the same aortic counterpulsation, but with a device that replaces the ascending aorta. For this reason reference in this specification to "compression of the aorta" includes compression

In a third aspect, the present invention provides a heart assist device adapted for implantation in a patient, the device including:-

a) an aortic compression means which includes an inflatable cuff and is so shaped and dimensioned that it is adapted to encircle and, when actuated, compress the aorta of a patient, the cuff being substantially C-shaped and including two free ends that are adapted to overlap when the cuff is placed around the aorta;

b) a fluid reservoir; and

c) pump means adapted to pump a fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means at least partly in counterpulsation with the patient's heart,

the fluid reservoir and the pump means are so shaped, dimensioned and interconnected that they are adapted to be wholly positioned within the chest cavity of the patient.

In a fourth aspect, the present invention provides a heart assist device adapted for implantation in a patient, the device including:-

a) an aortic compression means which includes an inflatable cuff and is so shaped and dimensioned that it is adapted to substantially encircle and, when actuated, compress the aorta of a patient, the cuff having two free ends, one of which includes an elongate tongue adapted for suturing or other connection in an overlapping relationship to the other end to retain the cuff in place around the aorta;

b) a fluid reservoir; and

c) pump means adapted to pump a fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means at least partly in counterpulsation with the patient's heart,

the fluid reservoir and the pump means are so shaped, dimensioned and interconnected that they are adapted to be wholly positioned within the chest cavity of the patient.

In a fifth aspect, the present invention provides a heart assist device adapted for implantation in a patient, the device including:-

a) an aortic compression means which, when actuated, compress the aorta of a patient;

b) a fluid reservoir; and

In a ninth aspect, the present invention provides an aortic compression means for use in a heart assist device, the aortic compression means including:

a) an elastic inflatable cuff adapted to be placed about the ascending aorta of a patient; and

b) a flexible, substantially inelastic, sheath adapted to extend around the cuff and at least assist in retaining it in position on the aorta,

wherein the cuff is substantially C-shaped and includes two free ends, one of the free ends includes an elongated tongue adapted for suturing or otherwise connected in an overlapping relationship to the other end to retain the device adjacent the aorta.

In a tenth aspect, the present invention provides a heart assist device including:

a) an aortic compression means adapted by its shape and dimensions to be placed around the ascending aorta of a patient; and

b) an actuation means to periodically actuate the aortic compression means in at least partial counterpulsation with the heart,

wherein the aortic compression means and the actuation means are placed wholly within the right chest cavity of the patient.

In an eleventh aspect, the present invention provides a heart assist device adapted for implantation wholly into a bodily cavity of a patient, the device including:

a) an aortic compression means adapted, when actuated, to compress an aorta of a patient;

b) a housing with an exterior surface;

c) a fluid reservoir in the housing, the fluid reservoir having a flexible exterior surface forming part of the housing exterior surface; and

d) a pump means adapted to pump a fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means at least partly in counterpulsation with the patient's heart,

wherein the fluid reservoir flexible exterior surface is adapted to contract during aortic compression and expand in the absence of aortic compression and is further adapted to be positioned substantially adjacent a flexible organ in the patient's bodily cavity.

Preferably, the bodily cavity is the thoracic cavity and the organ is the lung.

In a further aspect, the present invention provides an implantable system for assisting the functioning of the heart of a subject, the system including:

an implantable device for assisting the functioning of the heart of a subject, including:

means for externally engaging and compressing the aorta;

motive means responsive to control signal(s) for actuating and de-activating the compressing means cyclically to help blood pump through the aorta, wherein the compressing means and the motive means are fully implantable within the thoracic cavity of the subject and wherein the compressing means and/or motive means include means adapted for attachment to the aorta and/or surrounding tissue within the thoracic cavity of the subject;

sensing means adapted for sensing the heart and generating sensing signals;

control means responsive to the sensing signals for generating the control signal(s); and

a power source for providing power to the motive means.

The device of the invention may operate in countersynchronisation to the heart (counterpulsation).

An advantage of the device and system of the present invention is that the risk of limb ischemia associated with conventional IAB systems is avoided because there is no blood contact with the device whatsoever. Patient ambulation is also possible. Additionally the implantation technique used for the device of the invention is less invasive than those required for other devices. In particular, compared to the arrangement taught in US Patent No. 4,583,523, the device of the present invention provides a better outcome in term of reduced risk of infection, cosmesis and ease of implant and explant.

A further advantage of the device and system of the present invention is that there is little risk to the patient in the event of device failure. The device has the great advantage of being able to be weaned and turned off in the event of cardiac recovery. This is simply not possible with known LVADs. Furthermore if the heart shows signs of relapsing back into failure, the device can be switched back on.

The compressing means of the device of the present invention preferably includes a preshaped balloon cuff for wrapping around a portion of the aorta. Preferably, the balloon is configured longitudinally to fit the curve, that of a circular or oval arc, of the ascending aorta. In a particularly preferred form of the device of the present invention, the cross-section of the cuff is C-shaped, allowing wrapping of the cuff with some overlap around the aorta. Preferably, the cuff is shaped such that it does concentrically compress the length of enclosed aorta and spreads the compression forces

evenly, reducing any wear or fatigue on any one part of the aorta. The balloon cuff is enclosed within a flexible and non-elastic outer sleeve. The sleeve has an elongated "tongue" on one arm of the C-shaped cuff and this is passed around the aorta to be secured by suturing or other means on the outer aspect of the other arm of the C-shaped cuff. This arrangement stops the balloon inflation force from going outwards. Furthermore, the preshaped cuff and flexible sleeve are particularly designed to create a snug fit and low profile on the aorta, to reduce damage to the aorta and surrounding structures, and to create maximum efficiency of the device.

In a preferred form of the invention, the device is adapted for compression of the ascending aorta. An upper mid-line sternotomy provides easy surgical access to the ascending aorta and has the further advantage of not being very painful for the patient. A minimum incision is required in this procedure. In this mode of use of the device of the invention, the compressing means is preferably adapted to squeeze approximately 15-25 ml of blood from the ascending aorta in each compression cycle.

The cuff has a single inlet/outlet port for the fluid to move to inflate/deflate the balloon. The fluid used is preferably liquid, such as water or saline, as this is noncompressible and less likely to leak compared to gas. Furthermore, using a liquid allows a fully implantable device so that the patient can mobilize easily. The port and connecting tube to the motive means is of sufficient diameter and length to allow rapid emptying and filling of the cuff without generating too high compression pressures. The fluid must move within 0.15 sec for effective counterpulsation action. The compressive force emptying the cuff is the force exerted by the compressed aorta. This approximately 100 mmHg. A tube lumen of approximately 1 to 1.5 cm with a length of 3 to 8 cm allows 17 to 25 ml fluid to pass down a gradient of 100 mmHg in less than 0.15 sec. The compressive force filling the cuff is generated by the motive means, and this pressure gradient is approximately the same ie the motive means generates approximately 200 mmHg to allow the fluid to shift into the cuff in less than 0.15 sec.

The port more preferably has a trumpet-shaped or flanged opening into the cuff to spread the fluid more evenly into the balloon during inflation and to assist more rapid deflation. There may be a diffuser mounted within the lumen of the port to reduce the fluid force on the balloon cuff during inflation.

Preferably, the motive means drives the fluid via a fluid filled sac contained within the motive means. The motive means of the device of the invention may be any means that is capable of cyclically compressing and decompressing the fluid sac. The

motive means may be a mechanical or an electromechanical device. The motive means may be an electric motor/cam arrangement. The motive means may include spring mounted arms driven by a pulse of power to hinged solenoids or the like to drive the pressure plates towards each other and thereby compress the aorta. An example of a suitable motive means is an adaptation of the solenoid actuator described in US Patent No. 4,457,673, the relevant disclosure of which is incorporated herein by reference. The motive means may also be based on that used in the Novacor N100 Left Ventricular Assist System.

The motive means is preferably enclosed in an air-tight housing. The housing may have a flexible portion that allows for the fluid shift from the motive means – the flexible portion is presented toward the lung tissue and can thus move back and forth. More particularly the motive means is fully implanted within the thoracic cavity and a pressure compliance membrane "interfaces" with the lung surface. Alternatively the housing may be rigid and when the motive means is activated and the fluid sac compressed, a small vacuum is created within the housing. This vacuum has the advantage of increasing the pressure gradient for subsequent emptying of the cuff, to make emptying more rapid. The level of vacuum could be adjusted by accessing a transcutaneous gas reservoir linked to the housing. A final alternative is to have a external gas line from the motive means to allow gas exhaust, eliminating the need for a compliance chamber, but introducing a percutaneous line that has an increased risk of infection.

The motive means may be designed so that in the event of failure, it automatically goes into "off" with the fluid sac filled so that the aorta is not compressed, thus minimising risk to the patient.

The motive means may include or be associated with means for detecting speed and completeness of cuff filling and emptying, and of monitoring the fluid pressure within the connector tube, means for measuring arterial blood pressure or flow. The motive means may also act to record the ECG, having electrodes positioned on the housing or as separate wires attached to body tissues.

The means adapted for attachment to the aorta and/or surrounding tissue of the subject may be any suitable means. For example, the attachment means may be adapted for suturing and/or gluing the compressing means or motive means to the aorta or the surrounding tissue within the chest cavity. The attachment means may be suturing tabs. The attachment means may be apertures allowing ingrowth of tissue and/or surface

portions adapted to promote tissue growth into or onto the compressing means and/or the motive means so as to hold the device in position relative to the aorta. For example, the cuff may have a plurality of holes through which the cuff may be sutured to the aorta. The cuff may also have holes or slits to accommodate coronary artery bypass grafts to the ascending aorta. The motive means will sit within the chest cavity, preferably the right thoracic cavity, between the mediastinum and the right lung.

The sensor means may be means detecting a selected physiological event associated with heartbeat. The sensor means may be any means for producing an ECG. Means for detecting the action potentials of the cardiac muscles, for example electrodes, are well known to those skilled in the art and will not be described in detail here.

The control means may be any means capable of providing an output to actuate the motive means in response to signal(s) providing the sensor means.

The control means may provide signals to the motor means to countersynchronise compression of the aorta with the heart beat to provide counterpulsation, for example, aorta compression may commence with aortic valve closure (ventricular diastole), whilst aorta release occurs just prior to contraction/ejection (ventricular systole).

The power means may be an internal and/or external battery, or TET (transcutaneous electronic transfer).

De-activation of the compressing means may be timed to the R wave of the ECG and may be adapted for adjustment either manually or automatically. The dicrotic notch on the arterial pressure wave may provide the signal for actuation of the compressing means.

In yet a further aspect, the present invention provides a method for improving blood circulation in a subject, the method including implanting a device in accordance with the invention fully within the thoracic cavity of a subject, actuating the compressing means periodically in synchrony with the diastole period to compress the aorta; and alternating the period of actuation with periods of deactivation of the compressing means thereby allowing the aorta to return to its uncompressed shape.

The system and device of preferred embodiments of the invention allow relief/recovery from chronic heart failure whilst allowing the subject to move around freely without being constrained by a large external pumping device.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention will now be described, by way of examples only, with reference to the accompanying drawings in which:

Fig. 1a is a schematic drawing of a first embodiment of a heart assist device according to the invention implanted in the thoracic cavity of a subject;

Fig. 1b is an enlarged view of the device shown in Fig. 1a;

Fig. 2a is an enlarged perspective detailed view of the device shown in Fig. 1a;

Fig. 2b is a partial top view of the device shown in Fig. 1a;

Fig. 3 is top view of a second embodiment of a heart assist device according to the invention;

Fig. 4 is a top view of a third embodiment of a heart assist device according to the invention;

Fig. 5a is a top view of a fourth embodiment of a heart assist device according to the invention;

Fig. 5b is a perspective view of the device shown in Fig. 5a;

Fig. 6 is a block diagram of an embodiment of a cardiac assist system according to the invention;

Fig. 7 is a side view of an embodiment of an inflatable cuff;

Fig. 8 is a rear view of the cuff shown in Fig. 7;

Fig. 9a is a top view of the cuff shown in Fig. 7;

Fig. 9b is a top view of the cuff shown in Fig. 7 after application of an external sheath;

Fig. 10 is a front view of the cuff shown in Fig. 7;

Fig. 11 is a fifth embodiment of a heart assist device according to the invention;

Fig. 12 is a schematic side view of a sixth embodiment of a heart assist device according to the invention;

Fig. 13 is a schematic side view of a seventh embodiment of a heart assist device according to the invention;

Fig. 14 is an indication of an electrical cardiograph (ECG) readout, heart diastolic pressure (Pr.) and power supply (Po) for the device shown in Fig. 13;

Fig. 15 is a schematic side view of an eighth embodiment of a heart assist device according to the invention;

Fig. 16 is an exploded view of the pump housing of the device shown in Fig. 15;

Fig. 17 is a schematic cross sectional view of a ninth embodiment of a heart assist device according to the invention; and

Fig. 18 is a schematic view of a tenth embodiment of a heart assist device according to the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Fig. 1a to 2b are schematic drawings showing a first embodiment of a heart assist device 10 in accordance with the invention. The device 10 is suitable for complete implantation in the thoracic cavity of a subject 99 adjacent the ascending portion of the aorta 15, as shown. The device 10 includes an aortic compression means in the form of a hinged solenoid 2 (see Figs. 2a and 2b) in a housing 12. The solenoid 2 is driven by pulses of electrical power from a controller/battery 14 to actuate wedge-shaped compression plates 4 via arms 3. The wedge-shaped plates 4 surround the ascending portion of the aorta 15. When the plates 4 are actuated they approach each other and that part of the aorta 15 between the plates 4 is compressed. The plates 4 have a plurality of holes 6 that provide means for suturing the plates to the aorta 15 and permitting ingrowth of tissue therethrough.

Figs. 2a and 2b are detailed schematic drawings of the solenoid 2 which show that it includes two arcuate plates 26 hinged at 8. The plates 26 are shown in the de-activated (resting) position in Fig. 2a and are shown in the actuated position in Fig. 2b compressing the aorta 15. The plates 26 are soft form moulded and are actuated by the hinged solenoid 4 via arms 23.

Fig. 3 to 5b are schematic drawings of second to fourth embodiments of heart assist devices in accordance with the present invention.

In the second embodiment shown in Fig. 3, the compression plates 34 are actuated via arms 33, with each of the arms 33 being acted on by a respective rod solenoid 38 acting through springs 37 between the rod solenoid 38 and the respective arm 33.

In the third embodiment shown in Fig. 4, solenoids 48 act on deformable nitinol plates 44 connected together at either end 47 to encircle the aorta 15.

In the fourth embodiment shown in Fig. 5a and 5b, wedge-shaped plates 54 are connected together at one end 57 and each plate is actuated by solenoids 58 acting through arms 53. As best shown in Fig. 5b, the wedge-shaped plates 54 effectively conform to the shape of the ascending aorta 15.

Fig. 6 is a block diagram of an embodiment of a cardiac assist system constructed in accordance with the invention suitable for use with, for example, the cardiac assist device 10.

Initiation of the compression of the aorta 15 by the compression plates 4 is accomplished by energisation of the solenoid 2. This energisation is under the control of a control means 100 which activates the solenoid 2 of the motive means 1 in response to signals received from an ECG monitor 102 or systemic arterial blood pressure 103 or the like. The ECG monitor 102 and/or the control means 1 are preferably implanted but may be on the body of the subject 99.

In operation, de-activation of the compression plates 4 draws them apart and effectively unloads the left ventricle by allowing the aorta 15 to return to its usual circular shape. The expansion of the aorta 15 between the de-activated plates causes a pressure drop in the aorta 15, facilitating left ventricle ejection (ie unloading of the heart). After the heart has finished ejecting blood into the aorta 15 and the aortic valve closes, the plates 4 are activated to move them towards each other and compress the aorta 15 and thereby squeeze blood out of the volume of the aorta 15 compressed by the compression plates 4 and augment the diastolic pressure. Coronary artery blood flow to the left ventricle occurs predominantly in diastole so compression of the aorta 15 also augments coronary blood flow.

Figs. 7 to 10 show an aortic compression means in the form of a flexible hollow inflatable cuff 60. The cuff 60 is curved along its length so as to substantially replicate the curve of the aorta 15 adjacent thereto. The cuff 60 is shown in its de-activated (uninflated) state in Fig. 9a, and has two free ends 61 and 62 which are adapted to overlap when the cuff 60 is placed around the aorta. As best shown in Fig. 10, the cuff 60 is retained adjacent the aorta after implantation by suturing the two free ends together at 63. This also ensures that the cuff 60 is a snug fit around the aorta, when the aorta is in its usual circular shape.

Further, as best shown in Fig. 9b, a substantially inelastic, flexible sheath 65 is also preferably placed around the cuff 60. The sheath 65 assists in retaining the cuff 60 adjacent the aorta and inwardly concentrates the compression forces generated by inflation of the cuff 60, as indicated by arrows 66. The sheath 65 can also have free ends sutured together to retain it and the cuff 60 adjacent the aorta in addition to, or in place of, the cuff sutures 63. The sheath 65 is preferably made from DACRON (Trade Mark), KEVLAR (Trade Mark), TEFLON (Trade Mark), GORE-TEX (Trade Mark),

polyurethane or other flexible inelastic bio-compatible materials. The sheath 65 is preferably glued, fused or otherwise bonded to the cuff 60.

The cuff 60 also has a single inlet/outlet port 64 for the introduction of fluid to inflate the cuff 60 and thereby compress the aorta and the removal of fluid for the deflation of the cuff and relaxing of the aorta. The fluid is preferably water or an isotonic solution of salt or other low-viscosity, non-toxic liquid.

The fluid is actively pumped into the cuff 60 for inflation into the shape indicated in phantom in Fig. 9b. The cuff 60 can be actively deflated by suctioning the fluid from the cuff 60. Alternatively, the cuff 60 can be passively deflated by the blood pressure of the constricted aorta re-expanding and returning the cuff 60 to the state shown in Fig. 9a, which ejects the fluid from the cuff 60. It is preferable to actively deflate the cuff 60 as it gives better presystolic unloading of the heart and counteracts any high intrathoracic pressures, such as when the subject coughs. In either case, the natural resilience of the cuff 60 also assists in deflation by biasing the cuff 60 to the shape shown in Fig 9b.

In another embodiment of heart assist device (not shown), the compression plates 4 are used to squeeze the cuff 60. This embodiment can be configured to operate in two ways. Firstly, the plates 4 can provide a larger aortic compression and the cuff 60 a smaller aortic compression, either simultaneously or one after the other. This reduces the fluid requirements of the cuff 60. Secondly, the cuff 60 can be set at a fixed inflation and provide a cushion between the plates 4 and the aorta.

In other embodiments of cuff (not shown), the sheath is integrally formed with the cuff, preferably by moulding, or in the form of flexible, inelastic fibres embedded in the cuff.

Figs. 11 to 18 are schematic drawings of fifth to tenth embodiments of heart assist devices in accordance with the present invention that utilise the cuff 60 shown in Figures 7 to 10.

In the fifth embodiment shown in Fig. 11, the cuff 60 is closely coupled to a fluid-filled air-tight housing 70 that has therein a pump, in the form of rotatable impeller 71 and a pair of valves 72 and 73 for directing the flow of the impeller 71. The housing also includes an inlet/outlet 76 in fluid communication with the inlet/outlet port 64 of the cuff 60. A fluid reservoir is also provided in the housing 70 in the form of an internal portion 74 of the volume of the housing 70, as is a pressure compliance means, in the form of a substantially flexible portion of 75 of the housing 70.

In operation, energisation of the impeller 71 with the valves 72 and 73 in the position shown in Fig. 11 causes fluid to be actively withdrawn from the cuff 60, which allow the aorta to return to its usual circular shape. This fluid is pumped into the internal portion 74 of the housing 70 and causes the flexible portion 75 to expand to the position shown in Fig. 11. When the valves 71 and 73 are in the positions shown in phantom in Fig. 11 and the impeller 71 is energised, the fluid in the portion 74 is pumped into the cuff 60 to expand same and to compress the aorta. The removal of fluid from the portion 74 causes the flexible portion 75 to retract to the position shown in the phantom in Fig. 11. As with earlier embodiments, the control of the impeller and valves is in response to signals received from an ECG monitor or systemic arterial blood pressure or the like.

In the sixth embodiment shown in Fig. 12, the device has only a single valve 76. The aorta is compressed by positioning the valve 76 as shown in Fig. 12 and energising the impeller 71. When the valve 76 is moved to the position shown in phantom in Fig. 2 and impeller is de-energised the expanding aorta passively ejects the fluid back into the portion 74 of the housing 71 and causes the flexible portion 75 to expand to the position shown in phantom.

In the seventh embodiment shown in Fig. 13, the impeller 71 is driven in one direction to cause fluid flow in the direction indicated by the arrow to deflate the cuff 60 and expand the flexible portion 75. Reversing the direction of the impeller 71 causes the flexible portion 75 to retract to the position shown in phantom as fluid is displaced into the cuff 60 to inflate same. This embodiment requires variable power control to the motor driving the impeller 71 and a plot of the motor power requirements (Po) relative to the subject's electro cardiograph reading (ECG) and aortic pressure (Pr.) are shown in Fig. 14.

In the eighth embodiment shown in Figs. 15 and 16, the housing 71 has a rigid upper portion 71a and a partially rigid lower portion 71b that includes the flexible portion 75. A motor 77 is mounted in the lower portion 71b that drives a pair of rollers 78, each positioned on an end of a common shaft 79. The housing portion 71b also has a pair of upstanding guide posts 80 which are slidably received in corresponding holes in a swash plate 81. The swash plate 81 has a pair of cam formations 82 on its underside. A fluid-filled sac 83 is positioned between the swash plate 81 and the housing portion 71a. The interior of the sac 83 is in fluid communication with the interior of the cuff 60. Power is supplied to the motor 77 through line 84.

In operation, the motor 77 is energised to rotate the rollers 78, which ride along the cam formations 82 to drive the swash plate 81 upwards to compress the sac 83 and eject the fluid therein into the cuff 60 to inflate same. When the rollers 78 have passed the cams 82 the swash plate 81 returns to its original position and the expanding aorta passively ejects the fluid back into the sac 83. In an alternative embodiment (not shown), the rollers 78 are linked to the cam formations 82 to drive the swash plate 81 up and down and thereby actively inflate and actively deflate the cuff 60. As a further alternative, (not shown) a stepper motor(s) can be used to drive the swash plate.

In the ninth embodiment shown in Fig. 17, the housing 71 has a fluid filled sac 83 positioned between a pair of compression plates 84 which are hinged at 85 and driven by a solenoid 86. Energising the solenoid 86 brings the plates 84 together to squeeze the sac 83 and force the liquid therein into the cuff 60 to inflate same. De-energising the solenoid 86 draws the plates 84 apart and the expanding aorta passively ejects the fluid back into the sac 83. As with earlier embodiments, as the sac 83 inflates the flexible portion 75 of the housing 71 expands to accommodate the increase in pressure in the housing 71.

In the tenth embodiment shown in Fig. 18, the heart assist device includes a liquid pressure adjustment means, in the form of remote reservoir 90, connected between the cuff 60 and the reservoir 74. Liquid can be added to the heart assist device, via the remote reservoir 90, to adjust the liquid retained in the (de-activated) cuff 60 and thereby adjust the pressure therein. This allows the size of the cuff 60 to be adjusted to compensate for changes in the size of the aorta and/or the amount of aortic compression to be adjusted to, for example, wean the patient from the heart assist device. When the reservoir is positioned near the skin, its volume can be adjusted by using a needle to inject or withdraw liquid. When the reservoir is positioned near the heart assist device, its volume can be adjusted by adding or withdrawing liquid via a transcutaneous tube. The pressure in the reservoir 90 can also be sensed and automatically adjusted so as to maintain a predetermined pressure.

It will be appreciated that the system and device of the present invention, in their preferred forms, are designed to be simple with no blood contact and a much lower morbidity risk compared to LVADs. The device and system allows the heart to remain totally un-instrumented, and the device, by effective counterpulsation in the aorta, augments the cardiac output up to 15-20%. All natural blood pathways are maintained.

Pulsatile blood flow is also maintained. The patient is able to ambulate and there is no risk of leg ischaemia.

The present invention provides for long term relief and/or stabilization/ of or recovery from chronic heart failure. Moreover the present invention may be a suitable bridging device for transplantation.

The device and system of the above-described embodiments improve cardiac work efficiency by reducing the afterload (pressure/resistance to flow which the heart has to overcome to eject blood) during systole (ejection phase), by augmenting diastolic aortic blood pressure to maintain a greater mean arterial pressure, and by increasing left ventricular coronary artery blood flow during diastole.

The preferred embodiments of the heart assist device compress the ascending aorta. This is advantageous as the ascending aorta is less prone to disease than the descending aorta and, being closer to the heart, provides improved pumping efficiency and thus a smaller heart assist device.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. For example, although the invention has been described in specific reference to compression of the aorta, the devices, systems and methods of the present invention can equally be used for the compression of the pulmonary artery to effectively act as a right ventrical assist device, and the present invention extends to this alternative aspect. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

11. A device as claimed in claim 10, further including a pressure compliance means.

12. A device as claimed in claim 11, wherein the pressure compliance means forms part of the housing.

13. A device as claimed in claim 12, wherein the pressure compliance means is a substantially rigid portion of the housing downstream of the pump means, the portion being of sufficient rigidity so as to not deform inwardly during aortic compression nor deform outwardly in the absence of aortic compression.

14. A device as claimed in claim 12, wherein the pressure compliance means is a substantially flexible portion of the housing downstream of the pump means, the portion being of sufficient flexibility so as to deform inwardly during aortic compression and deform outwardly in the absence of aortic compression

15. A device as claimed in claim 14, wherein the flexible portion is adapted to be positioned in juxtaposition with a lung of the patient and deform outwardly to slightly compress the lung in the absence of aortic compression.

16. A device as claimed in any one of claims 5 to 15, wherein the cuff has a single inlet/outlet port.

17. A device as claimed in claim 16, wherein the port has a diffuser therein.

18. A device as claimed in claim 16 or 17, wherein the housing has an inlet/outlet port opening in fluid communication with the cuff inlet/outlet port.

19. A heart assist device adapted for implantation into a patient, the device including:

a) an aortic compression means which is curved along its length so as to substantially replicate the curve of the ascending aorta adjacent to the aortic compression means and is so shaped and dimensioned that it is adapted, when actuated, to compress the aorta of a patient;

b) a fluid reservoir; and

c) pump means adapted to pump a fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means at least partly in counterpulsation with the patient's heart,

the fluid reservoir and the pump means are so shaped, dimensioned and interconnected that they are adapted to be wholly positioned within the chest cavity of the patient.

31. A device as claimed in any one of the claims 19 to 30, wherein the pump means is adapted for active compression of the aortic compression means and active decompression of the aortic compression means.

32. A device as claimed in any one of claims 19 to 30, wherein the pump means is adapted for active compression of the aortic compression means and passive decompression of the aortic compression means.

33. A device as claimed in any one of claims 19 to 32, further including a liquid pressure adjustment means between the aortic compression means and the liquid reservoir and in fluid communication with the aortic compression means and the liquid reservoir.

34. A device as claimed in claim 33, wherein the liquid pressure adjustment means is a remote reservoir positioned near the patient's skin that is adapted for the receiving or the removal of liquid therein via a needle though the skin.

35. A device as claimed in claim 34, wherein the liquid pressure adjustment means is a remote reservoir positioned in the chest cavity that is adapted for the receiving or the removal of liquid therein via a transcutaneous tube connected thereto.

36. A device as claimed in claim 19, 20, 21 or 22, further including a means to sense the pressure in the liquid pressure adjustment means in the absence of aortic compression and alter the sensed pressure to a predetermined pressure.

37. An aortic compression means for use in a heart assist device, the aortic compression means including:

a) an elastic inflatable cuff adapted to be placed about the ascending aorta of a patient; and

b) a flexible, substantially inelastic, sheath adapted to extend around the cuff and at least assist in retaining it in position on the aorta,

wherein the aortic compression means is curved along its length so as to substantially replicate the curve of the ascending aorta adjacent to the aortic compression means.

38. An aortic compression means for use in a heart assist device, the aortic compression means including:

a) an elastic inflatable cuff adapted to be placed about the ascending aorta of a patient; and

b) a flexible, substantially inelastic, sheath adapted to extend around the cuff and at least assist in retaining it in position on the aorta,

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU00/00654

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61M 1/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
KEYWORDS

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4979936 A (Stephenson et al.) 25 December 1990 Column 6, line 24 - column 8, line 56; figures	1-4, 6-7, 10, 17, 21, 23-35, 31-36, 38-39, 42-47, 49-50, 53, 54, 57-60
Y		30
X	WO 92/08500 A (McGill University) 29 May 1992 Page 5, line 13 - page 11, line 24; figures	1-4, 6, 17, 47, 49-50, 54, 57-60
Y		30

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 August 2000	18 AUGUST 2000

Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	ROSEMARY LONGSTAFF Telephone No : (02) 6283 2637

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU00/00654

C (Continuation). **DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99/04833 A (Commissariat a l' Energie Atomique) 4 February 1999 Page 9, line 8 - page 13, line 16; figures	1-4, 6-7, 10, 17, 21-25, 31-35, 47, 49-50, 54, 57-60
X	EP 216042 A (Medtronic Inc.) 1 April 1987 Page 8, line 22 - page 10, line 12; Figure 1	47

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU00/00654

Box I Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos : 61

because they relate to subject matter not required to be searched by this Authority, namely:

Plant or animal varieties. (Article 34(4)(a)(i); Rule 67)

2. [ ] Claims Nos :

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos :

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See extra sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2. [X] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU00/00654

Supplemental Box
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: I

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-20, 55-60 are directed to a heart assist device adapted for implantation, comprising an aortic compression meansIt is considered that a pump means, a fluid reservoir and the aortic compression means being actuated at least partly in counterpulsation with the patient's heart comprise a first "special technical feature".

2. Claims 21-35 are directed to a heart assist device adapted for implantation comprising an aortic compression means. It is considered that a pump means, a liquid reservoir and the aortic compression means adapted to be positioned in close juxtaposition with one another within the chest cavity comprise a second "special technical feature".

3. Claims 36-46 are directed to an aortic compression means for use with a heart assist device. It is considered that an elastic inflatable cuff adapted to be placed about the ascending aorta and a flexible, substantially inelastic sheath adapted to extend around the cuff and at least assist in retaining it in position on the aorta comprise a third "special technical feature".

4. Claims 47-54 are directed to a heart assist device comprising an aortic compression means. It is considered that the compression means being adapted to be placed around the ascending aorta, an actuation means to periodically actuate the aortic compression means in at least partial counterpulsation with the patient's heart, the aortic compression means and actuation means being placed wholly within the chest cavity comprise a fourth "special technical feature".

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU00/00654

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member	
WO	9208500	US	5429584
WO	9904833	FR	2766373
EP	216042	US	4813952

END OF ANNEX

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 December 2000 (21.12.2000)

PCT

(10) International Publication Number
WO 00/76288 A3

(51) International Patent Classification[7]: A61M 1/12

(21) International Application Number: PCT/AU00/00654

(22) International Filing Date: 9 June 2000 (09.06.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PQ 0904 10 June 1999 (10.06.1999) AU

(71) Applicant *(for all designated States except US)*: **SUNSHINE HEART COMPANY PTY LTD** [AU/AU]; 28D Montague Street, Balmain, NSW 2041 (AU).

(72) Inventors; and

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(74) Agent: **SPRUSON & FERGUSON**; GPO Box 3898, Sydney, NSW 2001 (AU).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

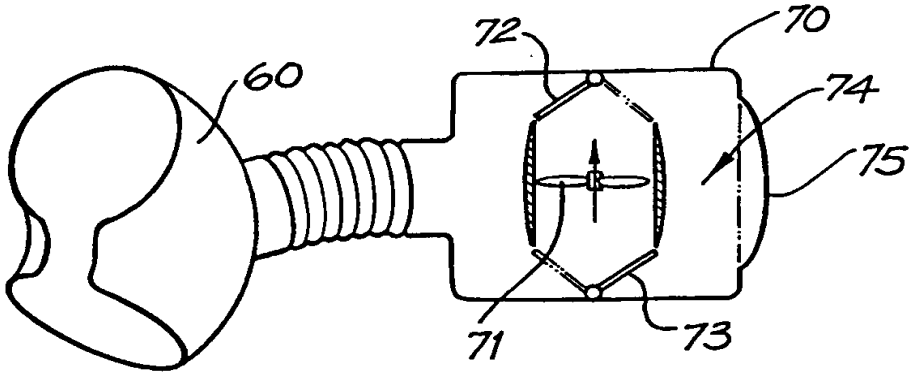
(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *With international search report.*

(88) Date of publication of the international search report:
25 May 2001

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: HEART ASSIST DEVICES, SYSTEMS AND METHODS



(57) Abstract: A heart assist device (10) adapted for implantation into a patient (99). The device (10) includes an aortic compression means (60) adapted, when actuated, to compress an aorta (15) of a patient (99), a fluid reservoir (74) and a pump means (71) adapted to pump a fluid from the fluid reservoir (74) to the aortic compression means (60) so as to actuate the aortic compression means (60) at least partly in counterpulsation with the patient's heart. The fluid reservoir (74) is adapted to be wholly positioned within the chest cavity of the patient (99).

WO 00/76288 A3

09/869923

PCT

REC'D 10 AUG 2001
WIPO PCT

14

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 507717c	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. **PCT/AU00/00654**	International Filing Date *(day/month/year)* 9 June 2000	Priority Date *(day/month/year)* 10 June 1999

International Patent Classification (IPC) or national classification and IPC

Int. Cl. [7] A61M 1/12

Applicant

SUNSHINE HEART COMPANY PTY LTD et al

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

[X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 7 sheet(s).

3. This report contains indications relating to the following items:

I	[X]	Basis of the report
II	[ ]	Priority
III	[ ]	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	[X]	Lack of unity of invention
V	[X]	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	[ ]	Certain documents cited
VII	[ ]	Certain defects in the international application
VIII	[X]	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
28 December 2000	1 August 2001
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **ROSEMARY LONGSTAFF** Telephone No. (02) 6283 2637

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU00/00654

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed.

☒ the description, pages , as originally filed,
pages **1-3, 5, 7-18,** received on **19 April 2001** with the letter of **18 April 2001,**
pages **4, 6,** received on **29 June 2001** with the letter of **28 June 2001**

☒ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages **19, 21-22, 24-26,** received on **19 April 2001** with the letter of **18 April 2001,**
pages **20, 23,** received on **29 June 2001** with the letter of **28 June 2001**

☒ the drawings, pages **1-10,** as originally filed,
pages , filed with the demand,
pages , received on with the letter of

☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:

The only feature common to all of the claims is an aortic compression means. However this common feature is generic in the art. Consequently the common feature does not constitute "a special technical feature" within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art. Since there exists no other common feature which can be considered as a special technical feature within the meaning of PCT Rule 13.2, second sentence, no technical relationship within the meaning of PCT Rule 13 between the different inventions can be seen. Consequently it appears that a posteriori, the claims do not satisfy the requirement of unity of invention.

In the specification, there are four inventions, as follows:

1. Claims 1-19 and 23-56 relate to an aortic compression means so shaped and dimensioned that it is adapted, when actuated, to compress the ascending aorta of a patient
2. Claims 20 and 21 relate to an inflatable cuff including two free ends which are adapted to overlap when the cuff is placed around the aorta.
3. Claim 22 relates to an aortic compression means wherein a pump means and a fluid reservoir are provided in a fluid filled, substantially air-tight housing.
4. Claim 57 relates to an aortic compression means including a fluid reservoir with a flexible erior exterior surface which is adapted to be placed adjacent a lung in the patient's chest cavity.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☒ all parts.

☐ the parts relating to claims Nos.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-59	YES
	Claims	NO
Inventive step (IS)	Claims 1-59	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-59	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

All claims are novel and involve an inventive step over the prior art. None of the cited documents, alone or in combination, disclose, or fairly suggest, all of the features of claims 1-59

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The invention is not clearly described. The "Summary of the Invention" gives thirteen "aspects" of the invention, with the only feature common to all these aspects being an aortic compression means. Such a means is well known in the art of heart assist devices.

HEART ASSIST DEVICES, SYSTEMS AND METHODS

FIELD OF THE INVENTION

The present invention relates to heart assist devices, systems and methods.

BACKGROUND OF THE INVENTION

Currently the only real options for improvement of end-stage heart failure are medical therapy, left ventricular assist devices (LVADs) and transplantation. ACE (Angiotensin Converting Enzyme) inhibitors unload the heart and prolong survival. LVADs pump blood and significantly improve life style and survival, but are complicated to implant, maintain and remove, with relatively high complications relating to bleeding, infection, thromboembolism, and device malfunction.

The transplant rate has stabilised at approximately 2,300 per year in the USA, being limited by organ availability. Transplantation achieves a 75% five year survival rate and a 65% ten year survival rate with significant improvements in functional class.

The number of people awaiting heart transplantation is steadily increasing and they are a sicker group, with increasing numbers requiring hospitalisation, intravenous ionotropes, short-term percutaneous trans-femoral intra-aortic balloon pumping and/or LVAD implantation.

The Institute of Medicine has estimated that by the year 2010, up to 70,000 patients will be candidates for permanent mechanical circulatory support systems.

Over the last ten years, LVADs have been well proven to save lives, acting as bridges to transplantation for critically ill patients. Recently, LVADs have been considered as alternatives to transplantation, and very recently, have been explanted in a few patients who have shown recovery. This latest realisation is starting to gather a lot of interest as researchers focus on recovery of the failing heart. LVADs totally unload the left ventricle and many believe that the heart will then recover. Moreover there is evidence beyond the few patients in whom devices have been removed that there is reversal in markers of heart failure. On the other hand, others have described an increase in myocardial fibrosis which raises a question of whether the heart is being unloaded too much.

The intra-aortic balloon pump (IABP) was first proposed in the 1960s as a method of partial support for the acutely failing heart, for example, after heart surgery or heart attack. It was built as a long thin catheter [10-14 Fr] with an elongated balloon at its tip [volume 30-40 ml]. The balloon was inserted via the femoral artery and inflated and

deflated in counter-pulsation with the heart beat. Inflation in diastole causes a diastolic pressure augmentation and increases coronary artery blood flow and deflating in systole (triggered by the R wave of the ECG) reduces the afterload, or the pressure head against which the left ventricle has to eject blood. Early investigators determined that the best and most efficient balloon position was closest to the heart, i.e., in the ascending aorta. However, in recent times, the balloon is positioned via the femoral artery in the descending aorta for short term (1-10 days) use. There is substantial proof beyond doubt that counterpulsation works very well in the short-term to assist hearts to recover when drugs (ionotropes etc.) are insufficient or inappropriate to support the cardiovascular system.

Intra-aortic balloon heart pumps operating in counterpulsation assist the heart function. When inflated, the balloon propels blood peripherally from within the aorta to improve blood circulation in the patient. Moreover, more blood is forced into the coronary arteries to help nourish and strengthen the heart muscle. However, the balloon comes into direct contact with the blood flowing into the aorta, which can cause damage to the blood cells and there is a risk of thromboembolism. In addition, current intra-aortic balloon pump systems are inflated by means of a tube passing through the body, the tube connecting the balloon to an external compressor. The opening for the tube to enter the body provides a possible site of infection or other injury. The tube is typically inserted into a groin vessel, the femoral artery, and there is a high risk of associated leg complications. Further, the patient is bedridden and cannot mobilize. Additionally, the use of a gas to inflate the balloon is not an entirely safe operation since any leakage of gas from the balloon into the blood stream could cause an air embolus.

Aortic compression (periaortic diastolic compression) has been described as a means to increase coronary blood flow. For example, US Patent No. 4,583,523 describes an implantable heart assist device including an elongated assembly extending transversely between the ribs of a patient from the rib cage to the aorta of the heart to be assisted. The assembly includes an aorta compressing device at the front end and a mounting device at the rear end thereof to support the device from the ribs of the patient. A motive device actuates and deactivates the compressing device alternatively to help pump blood through the aorta in a counterpulsation mode of operation. Although this device has advantages for many applications, it does require relatively complicated surgery to implant/explant the device, particularly in regard to the need to mount the device, including its motive means, to the ribs of the patient. Moreover the mounting arrangement and motive means of the device have to be positioned outside the rib cage, making the presence of the device

more noticeable to the patient. There is also substantial risk of infection with the device coming through the skin. Furthermore, because the device is attached/mounted to the ribs, there may be shear stresses on the aorta as the rib cage moves with inspiration/expiration. These stresses may cause untoward damage of the aorta.

US Patent No. 4,979,936 discloses an autologous biologic pump in the form of an apparatus using skeletal muscle formed into a pouch which then surrounds a collapsible, shape-retaining bladder. The bladder is connected to a second bladder enclosed in a sheath around a portion of the aorta. The bladders are filled with a fluid such that when the skeletal muscle contracts in response to an electrical stimulation, the fluid is forced from the first bladder into the second bladder sheathed around the aorta, expanding that second bladder and forcing the aorta to compress. Although this approach may be useful in some circumstances, it is doubtful that it is suitable for long term in that the muscle function would probably degrade over time. Furthermore, the muscle has to be "trained" for many weeks before the device can be relied on to assist blood circulation.

WO 99/04833 discloses a cardiac ventricle aid device which is implanted in the abdominal cavity with an aorta sleeve tube placed on, or inserted in, the descending aorta. A disadvantage of the disclosed device is it has a separate actuator and compliance chamber and its implantation is thus complicated. Another disadvantage is it is difficult to securely mount the device components to a structure in the abdominal cavity that is capable of supporting its weight. A further disadvantage is a number of vertebral arteries stem from the descending aorta which can be damaged during the implantation of the device.

It would be desirable to have a heart assist device that could be quickly and totally implanted in a relatively easy manner and with minimum trauma to the patient and to allow ambulation with low risk of complications. Also desirable would be a heart assist device that allows partial unloading of the heart longterm, augmenting the cardiac output of the native heart, and possibly allowing substantial recovery of the heart so that the device could be weaned. Moreover, it would be desirable for such a device to have no blood contacting surfaces, and not require cardiopulmonary bypass to implant the device. In a small proportion of patients however there will exist aortic disease making a periaortic device unsuitable. In these patients it would be desirable to be able to apply the same aortic counterpulsation, but with a device that replaces the ascending aorta. Such a device would require cardiopulmonary bypass and would be blood contacting, but has the same advantages of allowing partial unloading of the heart longterm, augmenting the

cardiac output of the native heart, and possibly allowing substantial recovery of the heart so that the device could be weaned.

It is an object of the present invention to satisfy one or more of the above desirable criteria.

SUMMARY OF THE INVENTION

In a first aspect, the present invention provides a heart assist device adapted for implantation into a patient, the device including

a) an aortic compression means adapted, when actuated, to compress an aorta of a patient;

b) a fluid reservoir; and

c) a pump means adapted to pump a fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means at least partly in counterpulsation with the patient's heart,

wherein the fluid reservoir is adapted to be wholly positioned within the chest cavity of the patient.

In a second aspect, the present invention provides a heart assist device adapted for implantation into a patient, the device including:

a) an aortic compression means adapted, when actuated, to compress the ascending aorta of a patient;

b) a liquid reservoir;

c) a pump means adapted to pump a liquid from the liquid reservoir to the aortic compression means so as to actuate the compression means, wherein the liquid reservoir and the aortic compression means are adapted to be positioned in close juxtaposition with one another within the chest cavity of the patient.

In a third aspect, the present invention provides an aortic compression means for use in a heart assist device, the aortic compression means including:

a) an elastic inflatable cuff adapted to be placed about the ascending aorta of a patient; and

b) a flexible, substantially inelastic, sheath adapted to extend around the cuff and at least assist in retaining it in position on the aorta.

In a fourth aspect, the present invention provides a heart assist device including:

a) an aortic compression means adapted to be placed around the ascending aorta of a patient; and

b) an actuation means to periodically actuate the aortic compression means in at least partial counterpulsation with the heart,

wherein the aortic compression means and the actuation means are placed wholly within the chest activity of the patient.

In a fifth aspect, the present invention provides a heart assist device adapted for implantation wholly into a bodily cavity of a patient, the device including:

a) an aortic compression means adapted, when actuated, to compress an aorta of a patient;

b) a housing with an exterior surface;

c) a fluid reservoir in the housing, the fluid reservoir having a flexible exterior surface forming part of the housing exterior surface; and

d) a pump means adapted to pump a fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means at least partly in counterpulsation with the patient's heart,

wherein the fluid reservoir flexible exterior surface is adapted to expand during aortic compression and constrict in the absence of aortic compression and is further adapted to be positioned substantially adjacent a flexible organ in the patient's bodily cavity.

Preferably, the bodily cavity is the thoracic cavity and the organ is the lung.

In a sixth aspect, the present invention provides a heart assist device adapted for implantation into a patient, the device including:

a) an elastic inflatable cuff adapted, when inflated, to compress an aorta of a patient;

b) a fluid reservoir;

c) a means for pumping a fluid from the fluid reservoir to the cuff so as to inflate the aortic compression means at least partly in counterpulsation with the patient's heart; and

d) a means for adjusting the volume of fluid in the cuff in the absence of aortic compression.

In a seventh aspect, the present invention provides a human or animal having a heart assist device according to any one of the preceding aspects of the invention implanted therein.

In a further aspect, the present invention provides an implantable system for assisting the functioning of the heart of a subject, the system including:

an implantable device for assisting the functioning of the heart of a subject, including:

means for externally engaging and compressing the aorta;

motive means responsive to control signal(s) for actuating and de-activating the compressing means cyclically to help blood pump through the aorta, wherein the compressing means and the motive means are fully implantable within the thoracic cavity of the subject and wherein the compressing means and/or motive means include means adapted for attachment to the aorta and/or surrounding tissue within the thoracic cavity of the subject;

sensing means adapted for sensing the heart and generating sensing signals;

control means responsive to the sensing signals for generating the control signal(s); and

a power source for providing power to the motive means.

The device of the invention may operate in countersynchronisation to the heart (counterpulsation).

An advantage of the device and system of the present invention is that the risk of limb ischemia associated with conventional IAB systems is avoided because there is no blood contact with the device whatsoever. Patient ambulation is also possible. Additionally the implantation technique used for the device of the invention is less invasive than those required for other devices. In particular, compared to the arrangement taught in US Patent No. 4,583,523, the device of the present invention provides a better outcome in term of reduced risk of infection, cosmesis and ease of implant and explant. A further advantage of the device and system of the present invention is that there is little risk to the patient in the event of device failure. The device has the great advantage of being able to be weaned and turned off in the event of cardiac recovery. This is simply not possible with known LVADs. Furthermore if the heart shows signs of relapsing back into failure, the device can be switched back on.

The compressing means of the device of the present invention preferably includes a preshaped balloon cuff for wrapping around a portion of the aorta. Preferably, the balloon is configured longitudinally to fit the curve, that of a circular or oval arc, of the ascending aorta. In a particularly preferred form of the device of the present invention, the cross-section of the cuff is C-shaped, allowing wrapping of the cuff with some overlap around the aorta. Preferably, the cuff is shaped such that it does

concentrically compress the length of enclosed aorta and spreads the compression forces evenly, reducing any wear or fatigue on any one part of the aorta. The balloon cuff is enclosed within a flexible and non-elastic outer sleeve. The sleeve has an elongated "tongue" on one arm of the C-shaped cuff and this is passed around the aorta to be secured by suturing or other means on the outer aspect of the other arm of the C-shaped cuff. This arrangement stops the balloon inflation force from going outwards. Furthermore, the preshaped cuff and flexible sleeve are particularly designed to create a snug fit and low profile on the aorta, to reduce damage to the aorta and surrounding structures, and to create maximum efficiency of the device.

In a preferred form of the invention, the device is adapted for compression of the ascending aorta. An upper mid-line sternotomy provides easy surgical access to the ascending aorta and has the further advantage of not being very painful for the patient. A minimum incision is required in this procedure. In this mode of use of the device of the invention, the compressing means is preferably adapted to squeeze approximately 15-25 ml of blood from the ascending aorta in each compression cycle.

The cuff has a single inlet/outlet port for the fluid to move to inflate/deflate the balloon. The fluid used is preferably liquid, such as water or saline, as this is noncompressible and less likely to leak compared to gas. Furthermore, using a liquid allows a fully implantable device so that the patient can mobilize easily. The port and connecting tube to the motive means is of sufficient diameter and length to allow rapid emptying and filling of the cuff without generating too high compression pressures. The fluid must move within 0.15 sec for effective counterpulsation action. The compressive force emptying the cuff is the force exerted by the compressed aorta. This approximately 100 mmHg. A tube lumen of approximately 1 to 1.5 cm with a length of 3 to 8 cm allows 17 to 25 ml fluid to pass down a gradient of 100 mmHg in less than 0.15 sec. The compressive force filling the cuff is generated by the motive means, and this pressure gradient is approximately the same ie the motive means generates approximately 200 mmHg to allow the fluid to shift into the cuff in less than 0.15 sec.

The port more preferably has a trumpet-shaped or flanged opening into the cuff to spread the fluid more evenly into the balloon during inflation and to assist more rapid deflation. There may be a diffuser mounted within the lumen of the port to reduce the fluid force on the balloon cuff during inflation.

Preferably, the motive means drives the fluid via a fluid filled sac contained within the motive means. The motive means of the device of the invention may be any means that is capable of cyclically compressing and decompressing the fluid sac. The

motive means may be a mechanical or an electromechanical device. The motive means may be an electric motor/cam arrangement. The motive means may include spring mounted arms driven by a pulse of power to hinged solenoids or the like to drive the pressure plates towards each other and thereby compress the aorta. An example of a suitable motive means is an adaptation of the solenoid actuator described in US Patent No. 4,457,673, the relevant disclosure of which is incorporated herein by reference. The motive means may also be based on that used in the Novacor N100 Left Ventricular Assist System.

The motive means is preferably enclosed in an air-tight housing. The housing may have a flexible portion that allows for the fluid shift from the motive means – the flexible portion is presented toward the lung tissue and can thus move back and forth. More particularly the motive means is fully implanted within the thoracic cavity and a pressure compliance membrane "interfaces" with the lung surface. Alternatively the housing may be rigid and when the motive means is activated and the fluid sac compressed, a small vacuum is created within the housing. This vacuum has the advantage of increasing the pressure gradient for subsequent emptying of the cuff, to make emptying more rapid. The level of vacuum could be adjusted by accessing a transcutaneous gas reservoir linked to the housing. A final alternative is to have a external gas line from the motive means to allow gas exhaust, eliminating the need for a compliance chamber, but introducing a percutaneous line that has an increased risk of infection.

The motive means may be designed so that in the event of failure, it automatically goes into "off" with the fluid sac filled so that the aorta is not compressed, thus minimising risk to the patient.

The motive means may include or be associated with means for detecting speed and completeness of cuff filling and emptying, and of monitoring the fluid pressure within the connector tube, means for measuring arterial blood pressure or flow. The motive means may also act to record the ECG, having electrodes positioned on the housing or as separate wires attached to body tissues.

The means adapted for attachment to the aorta and/or surrounding tissue of the subject may be any suitable means. For example, the attachment means may be adapted for suturing and/or gluing the compressing means or motive means to the aorta or the surrounding tissue within the chest cavity. The attachment means may be suturing tabs. The attachment means may be apertures allowing ingrowth of tissue and/or surface portions adapted to promote tissue growth into or onto the compressing means and/or the

motive means so as to hold the device in position relative to the aorta. For example, the cuff may have a plurality of holes through which the cuff may be sutured to the aorta. The cuff may also have hole or slits to accommodate coronary artery bypass grafts to the ascending aorta. The motive means will sit within the chest cavity, preferably the right thoracic cavity, between the mediastinum and the right lung.

The sensor means may be means detecting a selected physiological event associated with heartbeat. The sensor means may be any means for producing an ECG. Means for detecting the action potentials of the cardiac muscles, for example electrodes, are well known to those skilled in the art and will not be described in detail here.

The control means may be any means capable of providing an output to actuate the motive means in response to signal(s) providing the sensor means.

The control means may provide signals to the motor means to countersynchronise compression of the aorta with the heart beat to provide counterpulsation, for example, aorta compression may commence with aortic valve closure (ventricular diastole), whilst aorta release occurs just prior to contraction/ejection (ventricular systole).

The power means may be an internal and/or external battery, or TET (transcutaneous electronic transfer).

De-activation of the compressing means may be timed to the R wave of the ECG and may be adapted for adjustment either manually or automatically. The dicrotic notch on the arterial pressure wave may provide the signal for actuation of the compressing means.

In yet a further aspect, the present invention provides a method for improving blood circulation in a subject, the method including implanting a device in accordance with the invention fully within the thoracic cavity of a subject, actuating the compressing means periodically in synchrony with the diastole period to compress the aorta; and alternating the period of actuation with periods of deactivation of the compressing means thereby allowing the aorta to return to its uncompressed shape.

The system and device of the invention allow relief/recovery from chronic heart failure whilst allowing the subject to move around freely without being constrained by a large external pumping device.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention will now be described, by way of examples only, with reference to the accompanying drawings in which:

Fig. 1a is a schematic drawing of a first embodiment of a heart assist device according to the invention implanted in the thoracic cavity of a subject;

Fig. 1b is an enlarged view of the device shown in Fig. 1a;

Fig. 2a is an enlarged perspective detailed view of the device shown in Fig. 1a;

Fig. 2b is a partial top view of the device shown in Fig. 1a;

Fig. 3 is top view of a second embodiment of a heart assist device according to the invention;

Fig. 4 is a top view of a third embodiment of a heart assist device according to the invention;

Fig. 5a is a top view of a fourth embodiment of a heart assist device according to the invention;

Fig. 5b is a perspective view of the device shown in Fig. 5a;

Fig. 6 is a block diagram of an embodiment of a cardiac assist system according to the invention;

Fig. 7 is a side view of an embodiment of an inflatable cuff;

Fig. 8 is a rear view of the cuff shown in Fig. 7;

Fig. 9a is a top view of the cuff shown in Fig. 7;

Fig. 9b is a top view of the cuff shown in Fig. 7 after application of an external sheath;

Fig. 10 is a front view of the cuff shown in Fig. 7;

Fig. 11 is a fifth embodiment of a heart assist device according to the invention;

Fig. 12 is a schematic side view of a sixth embodiment of a heart assist device according to the invention;

Fig. 13 is a schematic side view of an seventh embodiment of a heart assist device according to the invention;

Fig. 14 is an indication of an electrical cardiograph (ECG) readout, heart diastolic pressure (Pr.) and power supply (Po) for the device shown in Fig. 13;

Fig. 15 is a schematic side view of an eighth embodiment of a heart assist device according to the invention;

Fig. 16 is an exploded view of the pump housing of the device shown in Fig. 15;

Fig. 17 is a schematic cross sectional view of a ninth embodiment of a heart assist device according to the invention; and

Fig. 18 is a schematic view of a tenth embodiment of a heart assist device according to the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Fig. 1a to 2b are schematic drawings showing a first embodiment of a heart assist device 10 in accordance with the invention. The device 10 is suitable for complete implantation in the thoracic cavity of a subject 99 adjacent the ascending portion of the aorta 15, as shown. The device 10 includes an aortic compression means in the form of a hinged solenoid 2 (see Figs. 2a and 2b) in a housing 12. The solenoid 2 is driven by pulses of electrical power from a controller/battery 14 to actuate wedge-shaped compression plates 4 via arms 3. The wedge-shaped plates 4 surround the ascending portion of the aorta 15. When the plates 4 are actuated they approach each other and that part of the aorta 15 between the plates 4 is compressed. The plates 4 have a plurality of holes 6 that provide means for suturing the plates to the aorta 15 and permitting ingrowth of tissue therethrough.

Figs. 2a and 2b are detailed schematic drawings of the solenoid 2 which show that it includes two arcuate plates 26 hinged at 8. The plates 26 are shown in the de-activated (resting) position in Fig. 2a and are shown in the actuated position in Fig. 2b compressing the aorta 15. The plates 26 are soft form moulded and are actuated by the hinged solenoid 4 via arms 23.

Fig. 3 to 5b are schematic drawings of second to fourth embodiments of heart assist devices in accordance with the present invention.

In the second embodiment shown in Fig. 3, the compression plates 34 are actuated via arms 33, with each of the arms 33 being acted on by a respective rod solenoid 38 acting through springs 37 between the rod solenoid 38 and the respective arm 33.

In the third embodiment shown in Fig. 4, solenoids 48 act on deformable nitinol plates 44 connected together at either end 47 to encircle the aorta 15.

In the fourth embodiment shown in Fig. 5a and 5b, wedge-shaped plates 54 are connected together at one end 57 and each plate is actuated by solenoids 58 acting through arms 53. As best shown in Fig. 5b, the wedge-shaped plates 54 effectively conform to the shape of the ascending aorta 15.

Fig. 6 is a block diagram of an embodiment of a cardiac assist system constructed in accordance with the invention suitable for use with, for example, the cardiac assist device 10.

Initiation of the compression of the aorta 15 by the compression plates 4 is accomplished by energisation of the solenoid 2. This energisation is under the control of a control means 100 which activates the solenoid 2 of the motive means 1 in response to

signals received from an ECG monitor 102 or systemic arterial blood pressure 103 or the like. The ECG monitor 102 and/or the control means 1 are preferably implanted but may be on the body of the subject 99.

In operation, de-activation of the compression plates 4 draws them apart and effectively unloads the left ventricle by allowing the aorta 15 to return to its usual circular shape. The expansion of the aorta 15 between the de-activated plates causes a pressure drop in the aorta 15, facilitating left ventricle ejection (ie unloading of the heart). After the heart has finished ejecting blood into the aorta 15 and the aortic valve closes, the plates 4 are activated to move them towards each other and compress the aorta 15 and thereby squeeze blood out of the volume of the aorta 15 compressed by the compression plates 4 and augment the diastolic pressure. Coronary artery blood flow to the left ventricle occurs predominantly in diastole so compression of the aorta 15 also augments coronary blood flow.

Figs. 7 to 10 show an aortic compression means in the form of a flexible hollow inflatable cuff 60. The cuff 60 is curved along its length so as to substantially replicate the curve of the aorta 15 adjacent thereto. The cuff 60 is shown in its de-activated (uninflated) state in Fig. 9a, and has two free ends 61 and 62 which are adapted to overlap when the cuff 60 is placed around the aorta. As best shown in Fig. 10, the cuff 60 is retained adjacent the aorta after implantation by suturing the two free ends together at 63. This also ensures that the cuff 60 is a snug fig around the aorta, when the aorta is in its usual circular shape.

Further, as best shown in Fig. 9b, a substantially inelastic, flexible sheath 65 is also preferably placed around the cuff 60. The sheath 65 assists in retaining the cuff 60 adjacent the aorta and inwardly concentrates the compression forces generated by inflation of the cuff 60, as indicated by arrows 66. The sheath 65 can also have free ends sutured together to retain it and the cuff 60 adjacent the aorta in addition to, or in place of, the cuff sutures 63. The sheath 65 is preferably made from DACRON (Trade Mark), KEVLAR (Trade Mark), TEFLON (Trade Mark), GORE-TEX (Trade Mark), polyurethane or other flexible inelastic bio-compatible materials. The sheath 65 is preferably glued, fused or otherwise bonded to the cuff 60.

The cuff 60 also has a single inlet/outlet port 64 for the introduction of fluid to inflate the cuff 60 and thereby compress the aorta and the removal of fluid for the deflation of the cuff and relaxing of the aorta. The fluid is preferably water or an isotonic solution of salt or other low-viscosity, non-toxic liquid.

The fluid is actively pumped into the cuff 60 for inflation into the shape indicated in phantom in Fig. 9b. The cuff 60 can be actively deflated by suctioning the fluid from the cuff 60. Alternatively, the cuff 60 can be passively deflated by the blood pressure of the constricted aorta re-expanding and returning the cuff 60 to the state shown in Fig. 9a, which ejects the fluid from the cuff 60. It is preferable to actively deflate the cuff 60 as it gives better presystolic unloading of the heart and counteracts any high intrathoracic pressures, such as when the subject coughs. In either case, the natural resilience of the cuff 60 also assists in deflation by biasing the cuff 60 to the shape shown in Fig 9b.

In another embodiment of heart assist device (not shown), the compression plates 4 are used to squeeze the cuff 60. This embodiment can be configured to operate in two ways. Firstly, the plates 4 can provide a larger aortic compression and the cuff 60 a smaller aortic compression, either simultaneously or one after the other. This reduces the fluid requirements of the cuff 60. Secondly, the cuff 60 can be set at a fixed inflation and provide a cushion between the plates 4 and the aorta.

In other embodiments of cuff (not shown), the sheath is integrally formed with the cuff, preferably by moulding, or in the form of flexible, inelastic fibres embedded in the cuff.

Figs. 11 to 18 are schematic drawings of fifth to tenth embodiments of heart assist devices in accordance with the present invention that utilise the cuff 60 shown in Figures 7 to 10.

In the fifth embodiment shown in Fig. 11, the cuff 60 is closely coupled to a fluid-filled air-tight housing 70 that has therein a pump, in the form of rotatable impeller 71 and a pair of valves 72 and 73 for directing the flow of the impeller 71. The housing also includes an inlet/outlet 76 in fluid communication with the inlet/outlet port 64 of the cuff 60. A fluid reservoir is also provided in the housing 70 in the form of an internal portion 74 of the volume of the housing 70, as is a pressure compliance means, in the form of a substantially flexible portion of 75 of the housing 70.

In operation, energisation of the impeller 71 with the valves 72 and 73 in the position shown in Fig. 11 causes fluid to be actively withdrawn from the cuff 60, which allow the aorta to return to its usual circular shape. This fluid is pumped into the internal portion 74 of the housing 70 and causes the flexible portion 75 to expand to the position shown in Fig. 11. When the valves 71 and 73 are in the positions shown in phantom in Fig. 11 and the impeller 71 is energised, the fluid in the portion 74 is pumped into the cuff 60 to expand same and to compress the aorta. The removal of fluid from the portion 74

causes the flexible portion 75 to retract to the position shown in the phantom in Fig. 11. As with earlier embodiments, the control of the impeller and valves is in response to signals received from an ECG monitor or systemic arterial blood pressure or the like.

In the sixth embodiment shown in Fig. 12, the device has only a single valve 76. The aorta is compressed by positioning the valve 76 as shown in Fig. 12 and energising the impeller 71. When the valve 76 is moved to the position shown in phantom in Fig. 2 and impeller is de-energised the expanding aorta passively ejects the fluid back into the portion 74 of the housing 71 and causes the flexible portion 75 to expand to the position shown in phantom.

In the seventh embodiment shown in Fig. 13, the impeller 71 is driven in one direction to cause fluid flow in the direction indicated by the arrow to deflate the cuff 60 and expand the flexible portion 75. Reversing the direction of the impeller 71 causes the flexible portion 75 to retract to the position shown in phantom as fluid is displaced into the cuff 60 to inflate same. This embodiment requires variable power control to the motor driving the impeller 71 and a plot of the motor power requirements (Po) relative to the subject's electro cardiograph reading (ECG) and aortic pressure (Pr.) are shown in Fig. 14.

In the eighth embodiment shown in Figs. 15 and 16, the housing 71 has a rigid upper portion 71a and a partially rigid lower portion 71b that includes the flexible portion 75. A motor 77 is mounted in the lower portion 71b that drives a pair of rollers 78, each positioned on an end of a common shaft 79. The housing portion 71b also has a pair of upstanding guide posts 80 which are slidably received in corresponding holes in a swash plate 81. The swash plate 81 has a pair of cam formations 82 on its underside. A fluid-filled sac 83 is positioned between the swash plate 81 and the housing portion 71a. The interior of the sac 83 is in fluid communication with the interior of the cuff 60. Power is supplied to the motor 77 through line 84.

In operation, the motor 77 is energised to rotate the rollers 78, which ride along the cam formations 82 to drive the swash plate 81 upwards to compress the sac 83 and eject the fluid therein into the cuff 60 to inflate same. When the rollers 78 have passed the cams 82 the swash plate 81 returns to its original position and the expanding aorta passively ejects the fluid back into the sac 83. In an alternative embodiment (not shown), the rollers 78 are linked to the cam formations 82 to drive the swash plate 81 up and down and thereby actively inflate and actively deflate the cuff 60. As a further alternative, (not shown) a stepper motor(s) can be used to drive the swash plate.

In the ninth embodiment shown in Fig. 17, the housing 71 has a fluid filled sac 83 positioned between a pair of compression plates 84 which are hinged at 85 and driven by a solenoid 86. Energising the solenoid 86 brings the plates 84 together to squeeze the sac 83 and force the liquid therein into the cuff 60 to inflate same. De-energising the solenoid 86 draws the plates 84 apart and the expanding aorta passively ejects the fluid back into the sac 83. As with earlier embodiments, as the sac 83 inflates the flexible portion 75 of the housing 71 expands to accommodate the increase in pressure in the housing 71.

In the tenth embodiment shown in Fig. 18, the heart assist device includes a liquid pressure adjustment means, in the form of remote reservoir 90, connected between the cuff 60 and the reservoir 74. Liquid can be added to the heart assist device, via the remote reservoir 90, to adjust the liquid retained in the (de-activated) cuff 60 and thereby adjust the pressure therein. This allows the size of the cuff 60 to be adjusted to compensate for changes in the size of the aorta and/or the amount of aortic compression to be adjusted to, for example, wean the patient from the heart assist device. When the reservoir is positioned near the skin, its volume can be adjusted by using a needle to inject or withdraw liquid. When the reservoir is positioned near the heart assist device, its volume can be adjusted by adding or withdrawing liquid via a transcutaneous tube. The pressure in the reservoir 90 can also be sensed and automatically adjusted so as to maintain a predetermined pressure.

It will be appreciated that the system and device of the present invention, in their preferred forms, are designed to be simple with no blood contact and a much lower morbidity risk compared to LVADs. The device and system allows the heart to remain totally un-instrumented, and the device, by effective counterpulsation in the aorta, augments the cardiac output up to 15-20%. All natural blood pathways are maintained. Pulsatile blood flow is also maintained. The patient is able to ambulate and there is no risk of leg ischaemia.

The present invention provides for long term relief and/or stabilization/ of or recovery from chronic heart failure. Moreover the present invention may be a suitable bridging device for transplantation.

The device and system of the above-described embodiments improve cardiac work efficiency by reducing the afterload (pressure/resistance to flow which the heart has to overcome to eject blood) during systole (ejection phase), by augmenting diastolic aortic blood pressure to maintain a greater mean arterial pressure, and by increasing left ventricular coronary artery blood flow during diastole.

The preferred embodiments of the heart assist device compress the ascending aorta. This is advantageous as the ascending aorta is less prone to disease than the descending aorta and, being closer to the heart, provides improved pumping efficiency and thus a smaller heart assist device.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. For example, although the invention has been described in specific reference to compression of the aorta, the devices, systems and methods of the present invention can equally be used for the compression of the pulmonary artery to effectively act as a right ventrical assist device, and the present invention extends to this alternative aspect. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

CLAIMS

1. A heart assist device adapted for implantation into a patient, the device including:

a) an aortic compression means adapted, when actuated, to compress an aorta of a patient;

b) a fluid reservoir; and

c) a pump means adapted to pump a fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means at least partly in counterpulsation with the patient's heart,

wherein the fluid reservoir is adapted to be wholly positioned within the chest cavity of the patient.

2. A device as claimed in claim 1, wherein the fluid is a liquid.

3. A device as claimed in claim 2, wherein the liquid is water or saline.

4. A device as claimed in any one of claims 1 to 3, wherein the aortic compression means is adapted to be placed about the patient's ascending aorta.

5. A device as claimed in any one of the preceding claims, wherein the aortic compression means is curved along its length so as to substantially replicate the curve of the aorta adjacent to the aortic compression means.

6. A device as claimed in any one of the preceding claims, wherein the aortic compression means includes an elastic inflatable cuff adapted to at least partly encircle the aorta.

7. A device as claimed in claim 6, wherein the cuff is adapted to completely encircle the aorta.

8. A device as claimed in claim in claim 6 or 7, wherein the cuff is substantially C-shaped and includes two free ends that are adapted to overlap when the cuff is placed around the aorta.

9. A device as claimed in claim 8, wherein one of the free ends includes an elongated tongue adapted for suturing in an overlapping relationship to the other end to retain the device adjacent the aorta.

10. A device as claimed in any one of claims 6 to 9, wherein the cuff is a snug fit around the aorta of the patient.

11. A device as claimed in any one of the preceding claims, wherein the pump means and the fluid reservoir are provided in a fluid-filled substantially air-tight housing.

12. A device as claimed in claim 11, further including a pressure compliance means.

13. A device as claimed in claim 12, wherein the pressure compliance means forms part of the housing.

14. A device as claimed in claim 13, wherein the pressure compliance means is a substantially rigid portion of the housing downstream of the pump means, the portion being of sufficient rigidity so as to not deform inwardly during aortic compression nor deform outwardly in the absence of aortic compression.

15. A device as claimed in claim 13, wherein the pressure compliance means is a substantially flexible portion of the housing downstream of the pump means, the portion being of sufficient flexibility so as to deform inwardly during aortic compression and deform outwardly in the absence of aortic compression

16. A device as claimed in claim 15, wherein the flexible portion is adapted to be positioned in juxtaposition with a lung of the patient and deform outwardly to slightly compress the lung in the absence of aortic compression.

17. A device as claimed in any one of claims 6 to 16, wherein the cuff has a single inlet/outlet port.

18. A device as claimed in claim 17, wherein the port has a diffuser therein.

19. A device as claimed in claim 17 or 18, wherein the housing has an inlet/outlet port opening in fluid communication with the cuff inlet/outlet port.

20. A device as claimed in any one of claims 11 to 19, wherein the housing and the cuff are closely coupled.

21. A heart assist device adapted for implantation into a patient, the device including:

a) an aortic compression means adapted, when actuated, to compress the ascending aorta of a patient;

b) a liquid reservoir;

c) a pump means adapted to pump a liquid from the liquid reservoir to the aortic compression means so as to actuate the compression means, wherein the liquid reservoir and the aortic compression means are adapted to be positioned in close juxtaposition with one another within the chest cavity of the patient.

22. A device as claimed in claim 21. wherein the distance between the liquid reservoir and the aortic compression means is no more than 6 cm.

23. A device as claimed in claim 21 or 22, further including a wide bore liquid conduit between the liquid reservoir and the aortic compression device.

24. A device as claimed in claim 23, wherein the liquid conduit has a minimum cross sectional area of at least 1 sq cm.

25. A device as claimed in any one of claims 21 to 24, further including a pressure compliance means.

26. A device as claimed in claim 25, wherein the liquid reservoir, the pump means and the pressure compliance means are provided in an air-tight housing.

27. A device as claimed in claim 26, wherein the housing is fluid-filled and the liquid reservoir is a portion of the interior of the housing.

28. A device as claimed in claim 26 or 27, wherein the pressure compliance means is a flexible portion of the housing adjacent the liquid reservoir.

29. A device as claimed in claim 28, wherein the flexible portion is adapted for positioning in juxtaposition with the lung of the patient.

30. A device as claimed in any one of the claims 21 to 29, wherein the pump means is adapted for active compression of the aortic compression means and active decompression of the aortic compression means.

31. A device as claimed in any one of claims 21 to 29, wherein the pump means is adapted for active compression of the aortic compression means and passive decompression of the aortic compression means.

32. A device as claimed in any one of claims 21 to 30, further including a liquid pressure adjustment means between the aortic compression means and the liquid reservoir and in fluid communication with the aortic compression means and the liquid reservoir.

33. A device as claimed in claim 32, wherein the liquid pressure adjustment means is a remote reservoir positioned near the patient's skin that is adapted for the receiving or the removal of liquid therein via a needle though the skin.

34. A device as claimed in claim 32, wherein the liquid pressure adjustment means is a remote reservoir positioned in the chest cavity that is adapted for the receiving or the removal of liquid therein via a transcutaneous tube connected thereto.

35. A device as claimed in claim 32, 33 or 34, further including a means to sense the pressure in the liquid pressure adjustment means in the absence of aortic compression and alter the sensed pressure to a predetermined pressure.

36. An aortic compression means for use in a heart assist device, the aortic compression means including:

a) an elastic inflatable cuff adapted to be placed about the ascending aorta of a patient; and

b) a flexible, substantially inelastic, sheath adapted to extend around the cuff and at least assist in retaining it in position on the aorta.

37. A device as claimed in claim 36, wherein the aortic compression means is curved along its length so as to substantially replicate the curve of the aorta adjacent to the aortic compression means.

38. A device as claimed in claim 36 or 37, wherein the cuff is adapted to at least partially encircle the aorta.

39. A device as claimed in claim 38, wherein the cuff is adapted to completely encircle the aorta of the patient.

40. A device as claimed in any one of claims 36 to 39, wherein the cuff is substantially C-shaped and includes two free ends that are adapted to overlap when the cuff is placed around the aorta.

41. A device as claimed in claim 40, wherein one of the free ends includes an elongated tongue adapted for suturing in an overlapping relationship to the other end to retain the device adjacent the aorta.

42. A device as claimed in any one of claims 36 to 41, wherein the cuff is a snug fit around the aorta of the patient.

43. A means as claimed in any one of claims 36 to 42, wherein the sheath is a snug fit around the cuff.

44. A device as claimed in any one of claims 36 to 43, wherein the cuff has a single inlet/outlet port.

45. A device as claimed in claim 44, wherein the sheath has an opening complimentary to the cuff inlet/outlet port.

46. A device as claimed in claim 36 to 45, wherein the cuff is inflatable to an enlarged pressurised configuration to compressing the aorta and relaxes to a static configuration to relax the aorta.

47. A heart assist device including:

a) an aortic compression means adapted to be placed around the ascending aorta of a patient; and

b) an actuation means to periodically actuate the aortic compression means in at least partial counterpulsation with the heart,

wherein the aortic compression means and the actuation means are placed wholly within the chest activity of the patient.

48. A device as claimed in claim 47, wherein the aortic compression means and the actuation means are closely coupled.

49. A device as claimed in claim 47 or 48, wherein the aortic compression means is inflatable to compress the aorta and the actuation means includes a pump means adapted to pump fluid into the aortic compression means to inflate same.

50. A device as claimed in claim 49, wherein the actuation means further includes a fluid reservoir and a pressure compensation means.

51. A device as claimed in claim 50, wherein the pump means, fluid reservoir and the pressure compensation means are contained in a fluid-filled air-tight housing.

52. A device as claimed in any one of claims 47 to 51, wherein the pump means is an impeller adapted to drive fluid from the fluid reservoir and the aortic compression means.

53. A device as claimed in any one of claims 49 to 51, wherein the pump means is a fluid-filled sac adapted to be compressed to drive fluid from the sac to the aortic compression means.

54. A device as claimed in any one of claims 47 to 53, wherein the aortic compression means is an inflatable cuff adapted for positioning about the aorta of the patient.

55. A heart assist device adapted for implantation wholly into a bodily cavity of a patient, the device including:

c) an aortic compression means adapted, when actuated, to compress an aorta of a patient;

d) a housing with an exterior surface;

c) a fluid reservoir in the housing, the fluid reservoir having a flexible exterior surface forming part of the housing exterior surface; and

d) a pump means adapted to pump a fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means at least partly in counterpulsation with the patient's heart,

wherein the fluid reservoir flexible exterior surface is adapted to expand during aortic compression and constrict in the absence of aortic compression and is further adapted to be positioned substantially adjacent a flexible organ in the patient's bodily cavity.

56. A device as claimed in claim 55, wherein the bodily cavity is the thoracic cavity and the organ is the lung.

57. A heart assist device adapted for implantation into a patient, the device including:

a) an elastic inflatable cuff adapted, when inflated, to compress an aorta of a patient;

b) a fluid reservoir;

c) a means for pumping a fluid from the fluid reservoir to the cuff so as to inflate the aortic compression means at least partly in counterpulsation with the patient's heart; and

d) a means for adjusting the volume of fluid in the cuff in the absence of aortic compression.

58. A device as claimed in claim 57, wherein the volume adjusting means is disposed between the cuff and the reservoir and is in fluid communication with the cuff and the reservoir.

59. A device as claimed in claim 57 or 58, wherein the volume adjusting means is a remote reservoir positioned near the patient's skin that is adapted for the receiving or the removal of fluid therein via a needle though the skin.

60. A device as claimed in claim 57 or 58, wherein the volume adjusting means is a remote reservoir positioned in the chest cavity that is adapted for the receiving or the removal of fluid therein via a transcutaneous tube connected thereto.

61. A human or animal having a heart assist device according to any one of the preceding claims implanted therein.

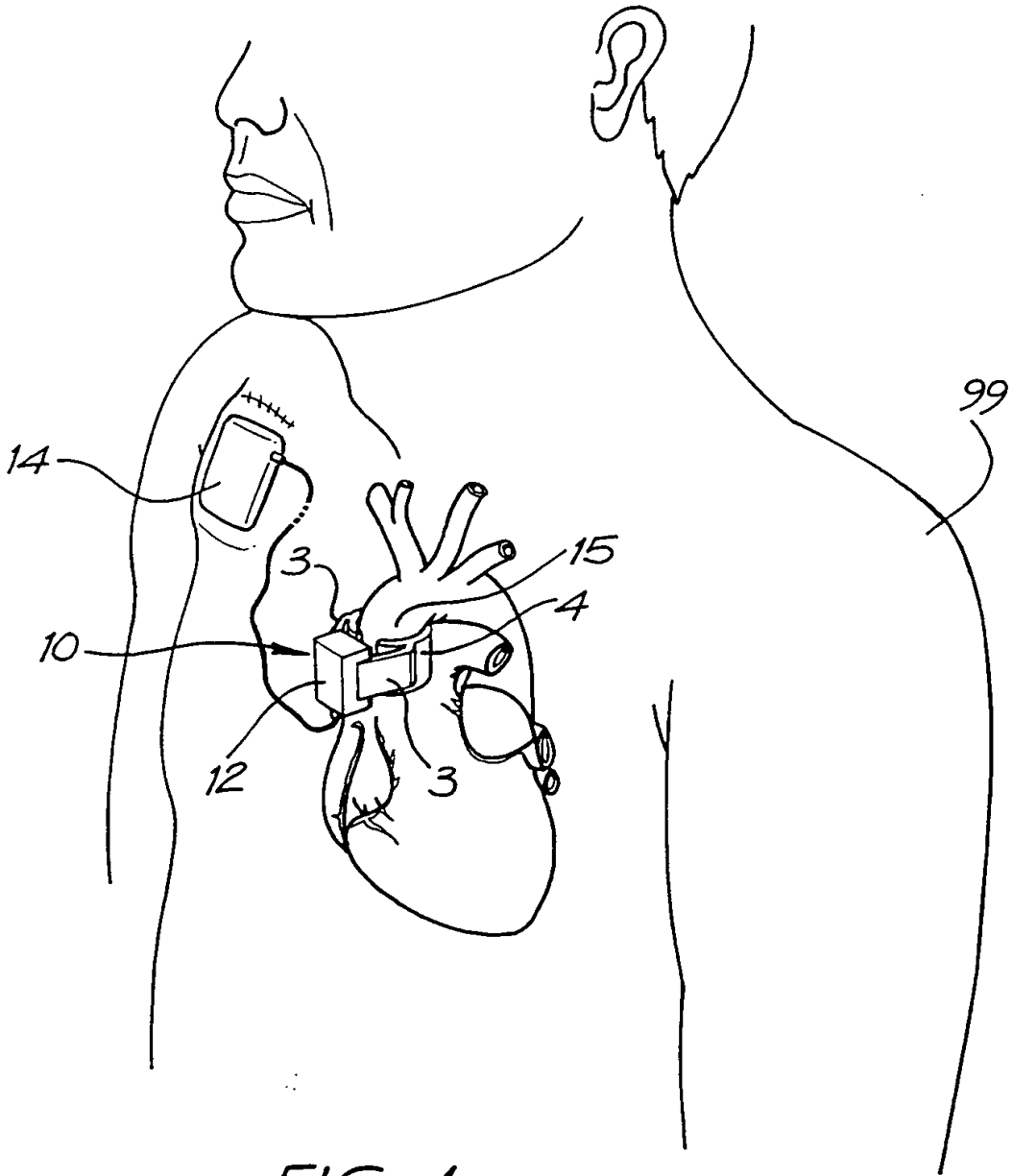


FIG. 1a

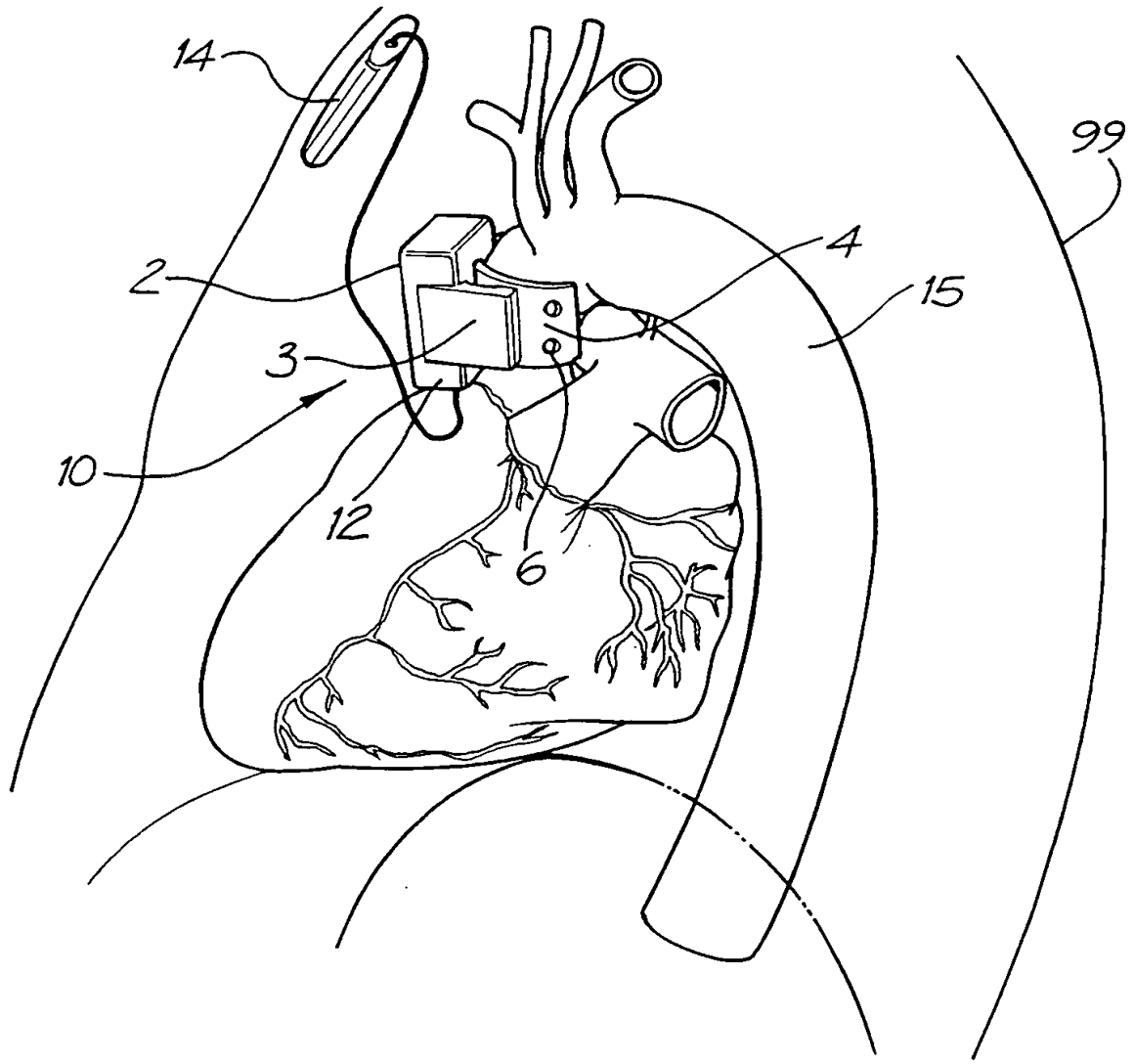


FIG. 1b

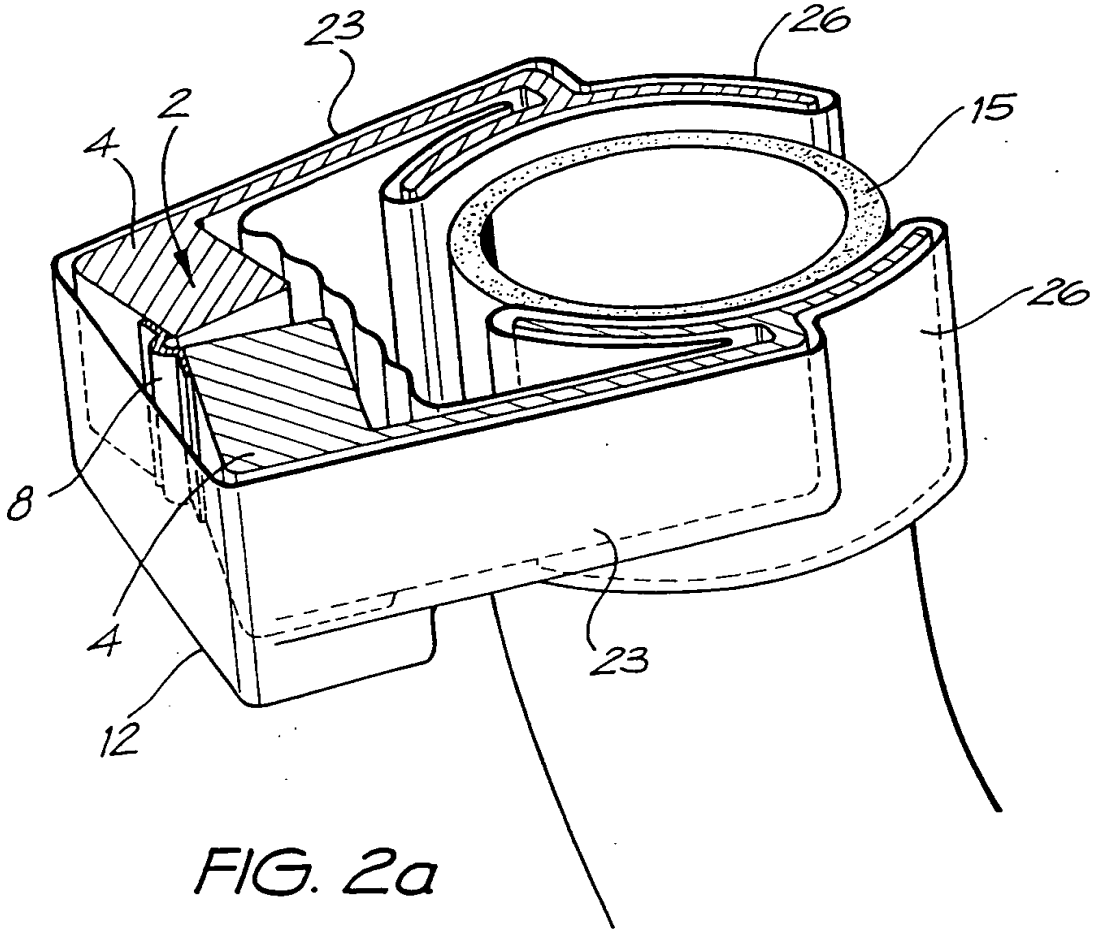


FIG. 2a

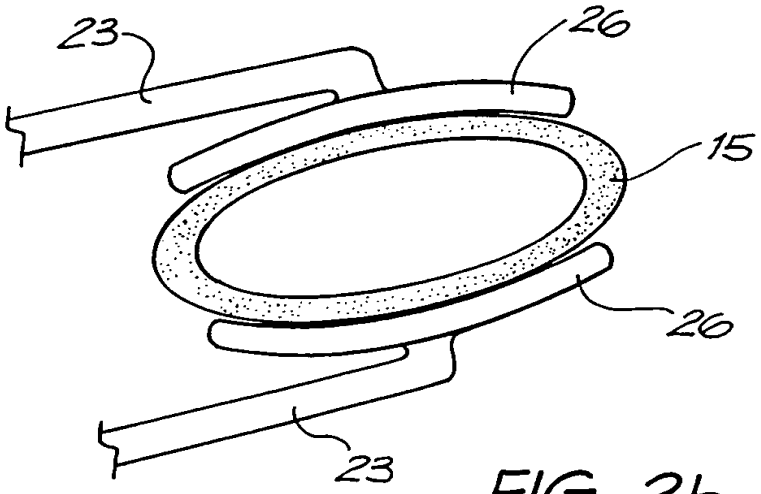


FIG. 2b

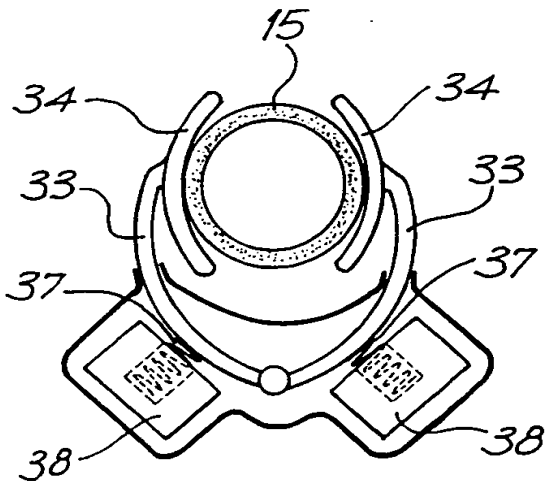


FIG. 3

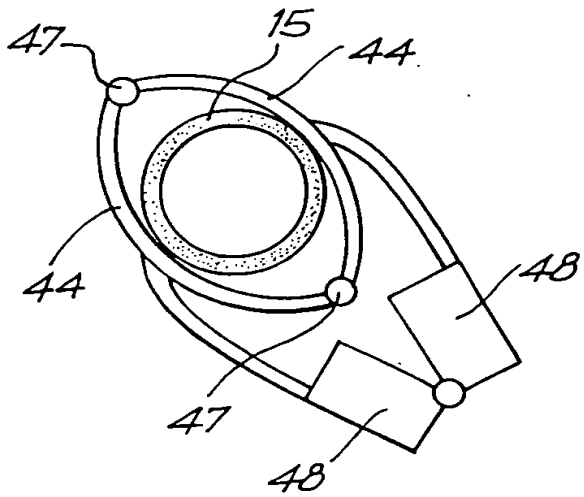


FIG. 4

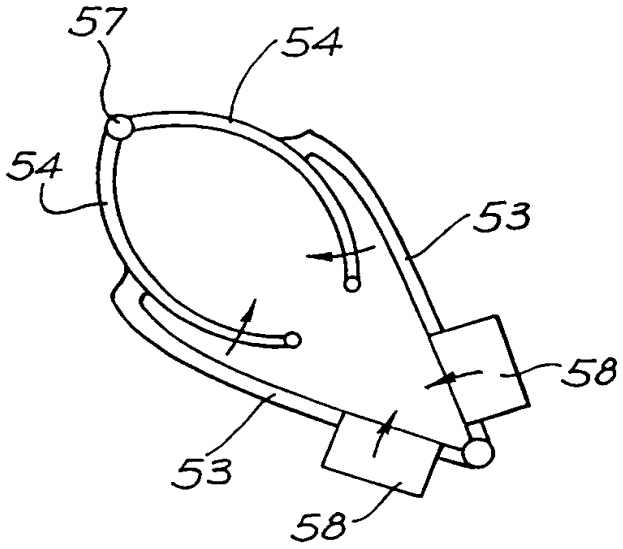


FIG. 5a

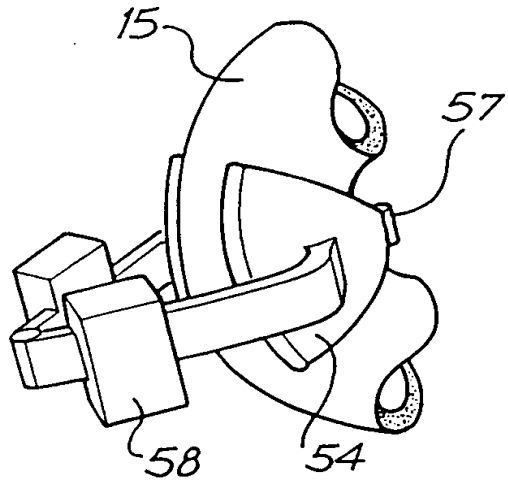


FIG. 5b

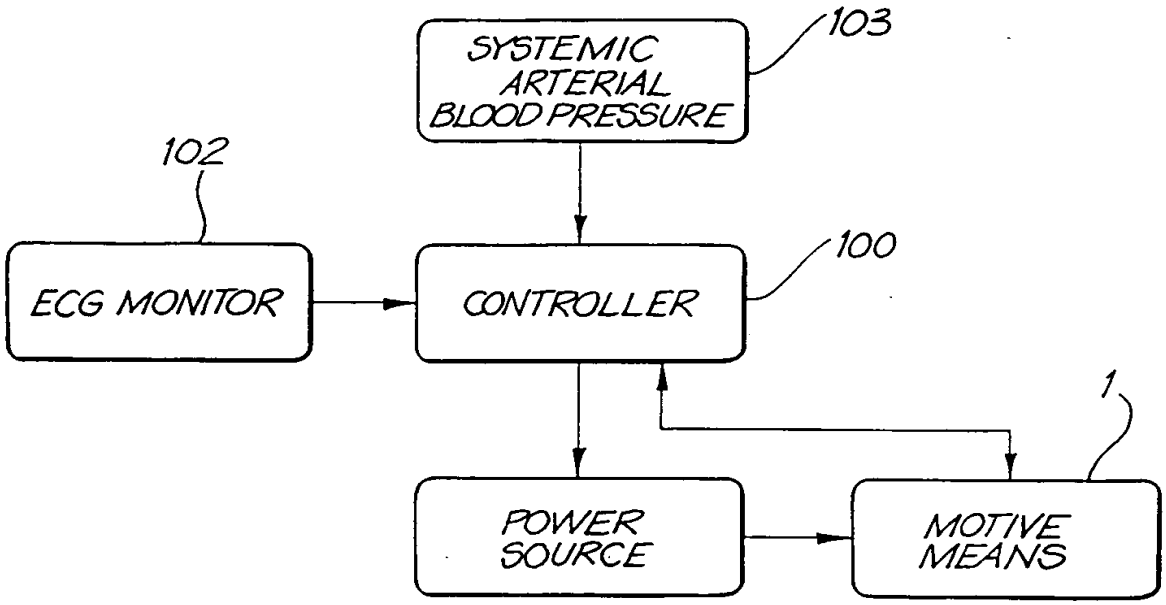

SYSTEMIC ARTERIAL BLOOD PRESSURE
103
102
ECG MONITOR
CONTROLLER
100
1
POWER SOURCE
MOTIVE MEANS

FIG. 6

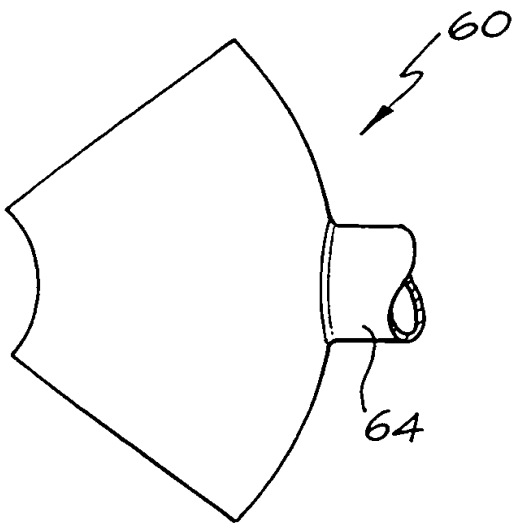


FIG. 7

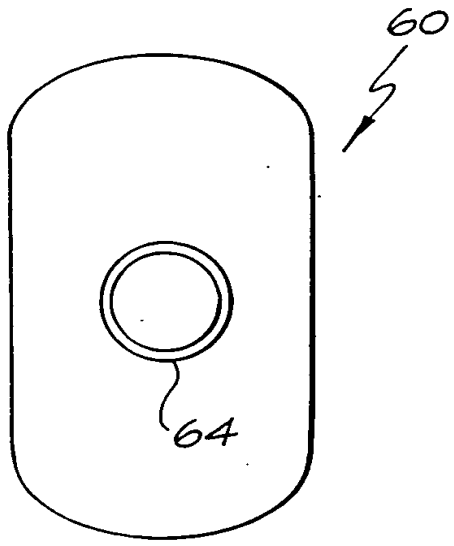


FIG. 8

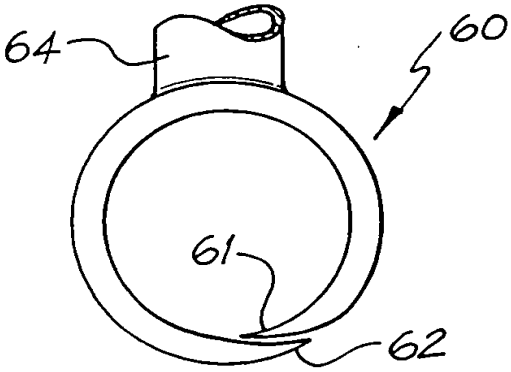


FIG. 9a

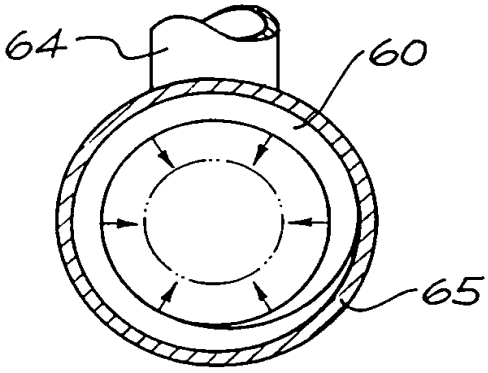


FIG. 9b

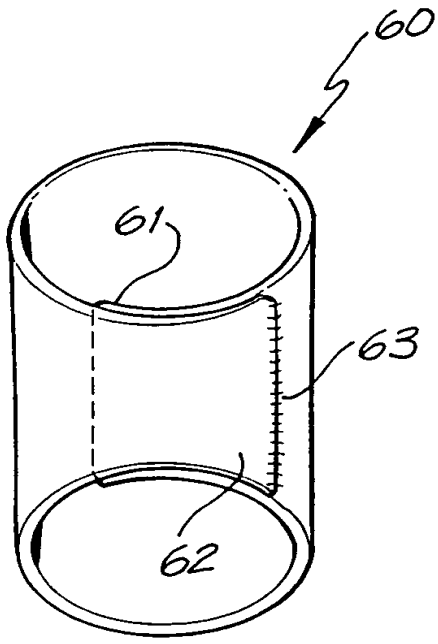


FIG. 10

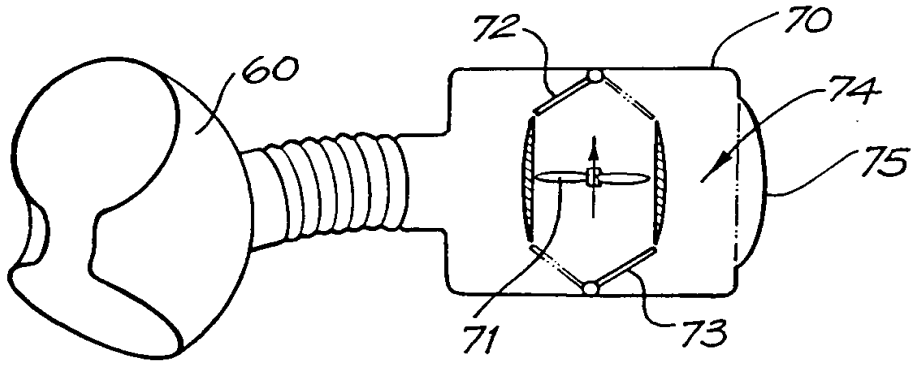


FIG. 11

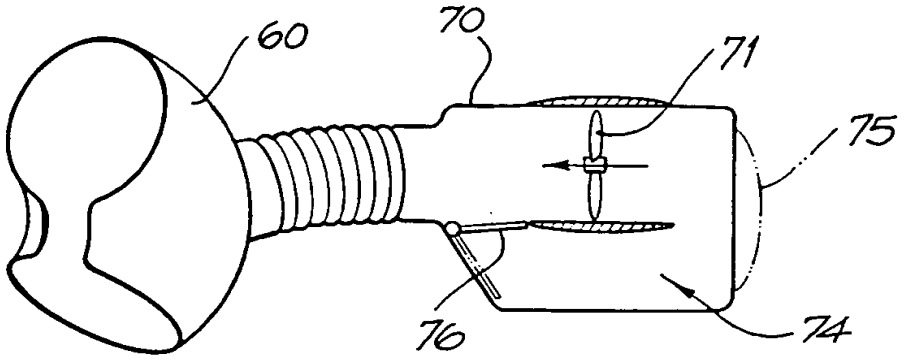


FIG. 12

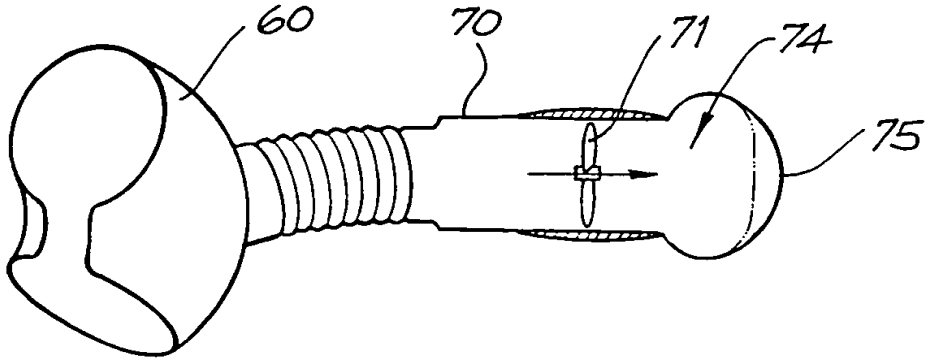


FIG. 13

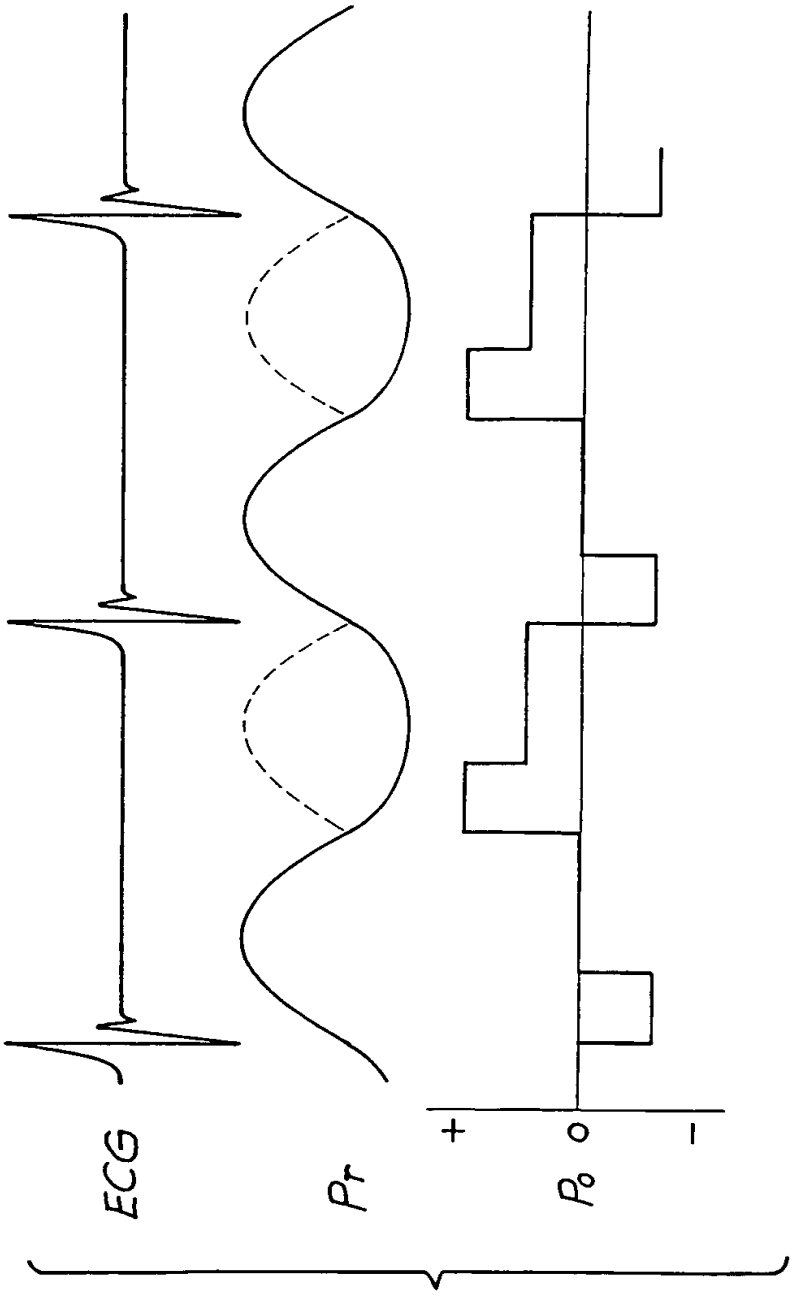


FIG. 14

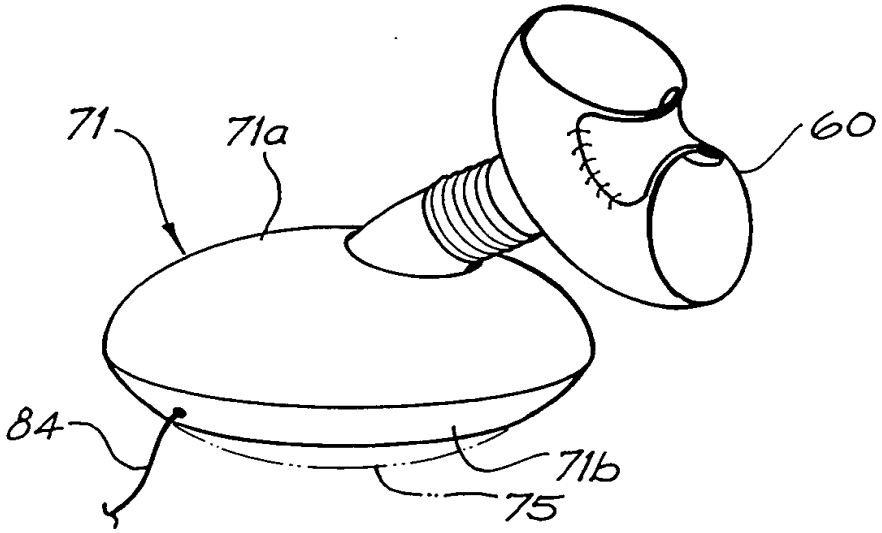


FIG. 15

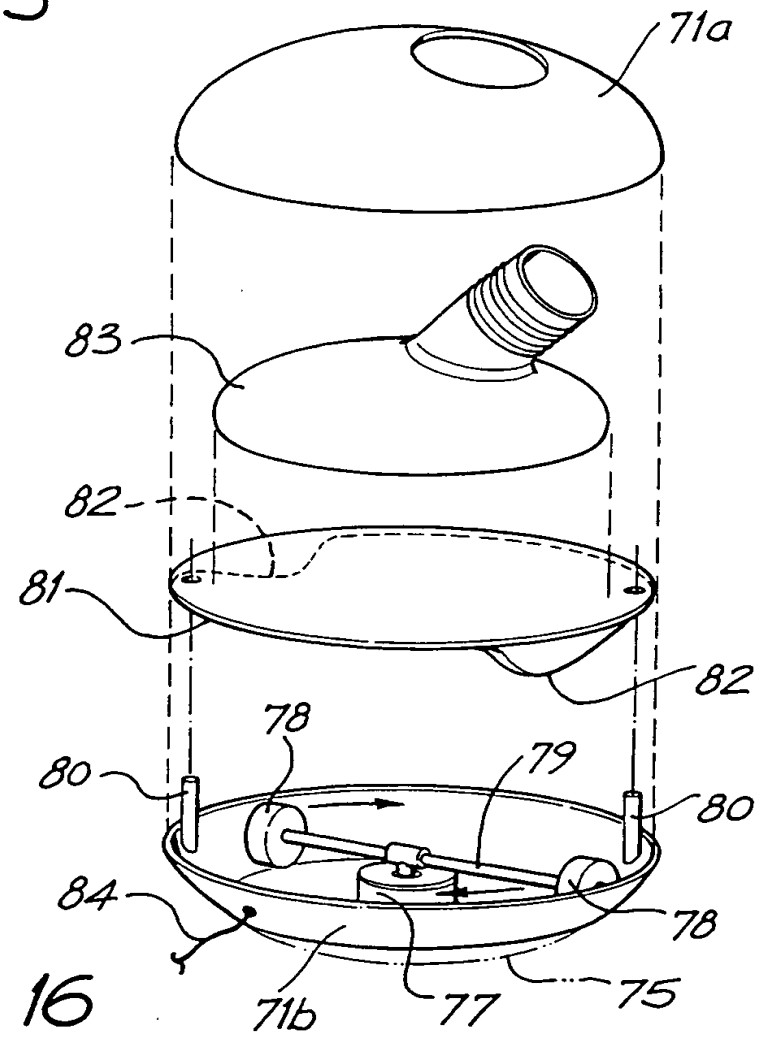


FIG. 16

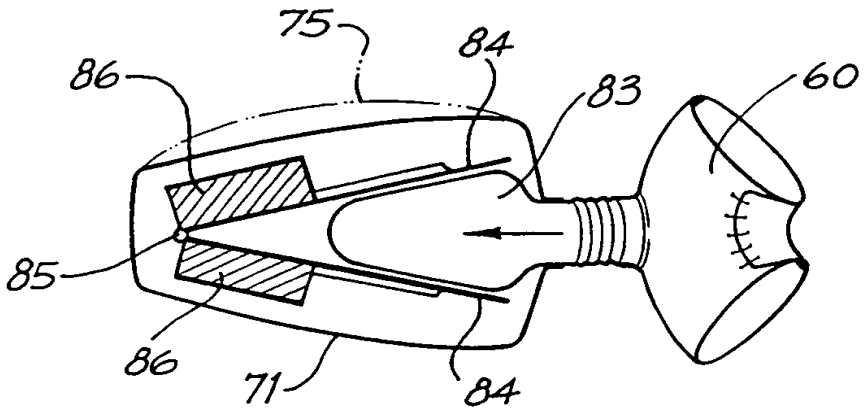


FIG. 17

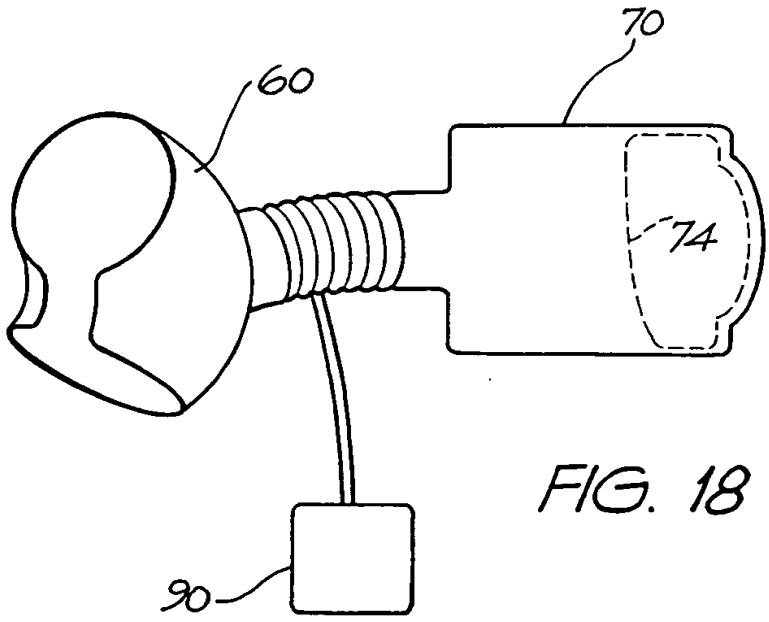


FIG. 18

CLAIMS

1. A heart assist device adapted for implantation into a patient, the device including:

a) an aortic compression means adapted, when actuated, to compress an aorta of a patient;

b) a fluid reservoir; and

c) a pump means adapted to pump a fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means at least partly in counterpulsation with the patient's heart,

wherein the fluid reservoir is adapted to be wholly positioned within the chest cavity of the patient.

2. A device as claimed in claim 1, wherein the fluid is a liquid.

3. A device as claimed in claim 2, wherein the liquid is water or saline.

4. A device as claimed in any one of claims 1 to 3, wherein the aortic compression means is adapted to be placed about the patient's ascending aorta.

5. A device as claimed in any one of the preceding claims, wherein the aortic compression means is curved along its length so as to substantially replicate the curve of the aorta adjacent to the aortic compression means.

6. A device as claimed in any one of the preceding claims, wherein the aortic compression means includes an elastic inflatable cuff adapted to at least partly encircle the aorta.

7. A device as claimed in claim 6, wherein the cuff is adapted to completely encircle the aorta.

8. A device as claimed in claim in claim 6 or 7, wherein the cuff is substantially C-shaped and includes two free ends that are adapted to overlap when the cuff is placed around the aorta.

9. A device as claimed in claim 8, wherein one of the free ends includes an elongated tongue adapted for suturing in an overlapping relationship to the other end to retain the device adjacent the aorta.

10. A device as claimed in any one of claims 6 to 9, wherein the cuff is a snug fit around the aorta of the patient.

11. A device as claimed in any one of the preceding claims, wherein the pump means and the fluid reservoir are provided in a fluid-filled substantially air-tight housing.

12. A device as claimed in claim 11, further including a pressure compliance means.

13. A device as claimed in claim 12, wherein the pressure compliance means forms part of the housing.

14. A device as claimed in claim 13, wherein the pressure compliance means is a substantially rigid portion of the housing downstream of the pump means, the portion being of sufficient rigidity so as to not deform inwardly during aortic compression nor deform outwardly in the absence of aortic compression.

15. A device as claimed in claim 13, wherein the pressure compliance means is a substantially flexible portion of the housing downstream of the pump means, the portion being of sufficient flexibility so as to deform inwardly during aortic compression and deform outwardly in the absence of aortic compression

16. A device as claimed in claim 15, wherein the flexible portion is adapted to be positioned in juxtaposition with a lung of the patient and deform outwardly to slightly compress the lung in the absence of aortic compression.

17. A device as claimed in any one of claims 6 to 16, wherein the cuff has a single inlet/outlet port.

18. A device as claimed in claim 17, wherein the port has a diffuser therein.

19. A device as claimed in claim 17 or 18, wherein the housing has an inlet/outlet port opening in fluid communication with the cuff inlet/outlet port.

20. A device as claimed in any one of claims 11 to 19, wherein the housing and the cuff are closely coupled.

21. A heart assist device adapted for implantation into a patient, the device including:

a) an aortic compression means adapted, when actuated, to compress the ascending aorta of a patient;

b) a liquid reservoir;

c) a pump means adapted to pump a liquid from the liquid reservoir to the aortic compression means so as to actuate the compression means, wherein the liquid reservoir and the aortic compression means are adapted to be positioned in close juxtaposition with one another within the chest cavity of the patient.

22. A device as claimed in claim 21, wherein the distance between the liquid reservoir and the aortic compression means is no more than 6 cm.

23. A device as claimed in claim 21 or 22, further including a wide bore liquid conduit between the liquid reservoir and the aortic compression device.

24. A device as claimed in claim 23, wherein the liquid conduit has a minimum cross sectional area of at least 1 sq cm.

25. A device as claimed in any one of claims 21 to 24, further including a pressure compliance means.

26. A device as claimed in claim 25, wherein the liquid reservoir, the pump means and the pressure compliance means are provided in an air-tight housing.

27. A device as claimed in claim 26, wherein the housing is fluid-filled and the liquid reservoir is a portion of the interior of the housing.

28. A device as claimed in claim 26 or 27, wherein the pressure compliance means is a flexible portion of the housing adjacent the liquid reservoir.

29. A device as claimed in claim 28, wherein the flexible portion is adapted for positioning in juxtaposition with the lung of the patient.

30. A device as claimed in any one of the claims 21 to 29, wherein the pump means is adapted for active compression of the aortic compression means and active decompression of the aortic compression means.

31. A device as claimed in any one of claims 21 to 29, wherein the pump means is adapted for active compression of the aortic compression means and passive decompression of the aortic compression means.

32. A device as claimed in any one of claims 21 to 30, further including a liquid pressure adjustment means between the aortic compression means and the liquid reservoir and in fluid communication with the aortic compression means and the liquid reservoir.

33. A device as claimed in claim 32, wherein the liquid pressure adjustment means is a remote reservoir positioned near the patient's skin that is adapted for the receiving or the removal of liquid therein via a needle though the skin.

34. A device as claimed in claim 32, wherein the liquid pressure adjustment means is a remote reservoir positioned in the chest cavity that is adapted for the receiving or the removal of liquid therein via a transcutaneous tube connected thereto.

35. A device as claimed in claim 32, 33 or 34, further including a means to sense the pressure in the liquid pressure adjustment means in the absence of aortic compression and alter the sensed pressure to a predetermined pressure.

36. An aortic compression means for use in a heart assist device, the aortic compression means including:

a) an elastic inflatable cuff adapted to be placed about the ascending aorta of a patient; and

b) a flexible, substantially inelastic, sheath adapted to extend around the cuff and at least assist in retaining it in position on the aorta.

37. A device as claimed in claim 36, wherein the aortic compression means is curved along its length so as to substantially replicate the curve of the aorta adjacent to the aortic compression means.

38. A device as claimed in claim 36 or 37, wherein the cuff is adapted to at least partially encircle the aorta.

39. A device as claimed in claim 38, wherein the cuff is adapted to completely encircle the aorta of the patient.

40. A device as claimed in any one of claims 36 to 39, wherein the cuff is substantially C-shaped and includes two free ends that are adapted to overlap when the cuff is placed around the aorta.

41. A device as claimed in claim 40, wherein one of the free ends includes an elongated tongue adapted for suturing in an overlapping relationship to the other end to retain the device adjacent the aorta.

42. A device as claimed in any one of claims 36 to 41, wherein the cuff is a snug fit around the aorta of the patient.

43. A means as claimed in any one of claims 36 to 42, wherein the sheath is a snug fit around the cuff.

44. A device as claimed in any one of claims 36 to 43, wherein the cuff has a single inlet/outlet port.

45. A device as claimed in claim 44, wherein the sheath has an opening complimentary to the cuff inlet/outlet port.

46. A device as claimed in claim 36 to 45, wherein the cuff is inflatable to an enlarged pressurised configuration to compressing the aorta and relaxes to a static configuration to relax the aorta.

47. A heart assist device including:

a) an aortic compression means adapted to be placed around the ascending aorta of a patient; and

b) an actuation means to periodically actuate the aortic compression means in at least partial counterpulsation with the heart,

wherein the aortic compression means and the actuation means are placed wholly within the chest activity of the patient.

48. A device as claimed in claim 47, wherein the aortic compression means and the actuation means are closely coupled.

49. A device as claimed in claim 47 or 48, wherein the aortic compression means is inflatable to compress the aorta and the actuation means includes a pump means adapted to pump fluid into the aortic compression means to inflate same.

50. A device as claimed in claim 49, wherein the actuation means further includes a fluid reservoir and a pressure compensation means.

51. A device as claimed in claim 50, wherein the pump means, fluid reservoir and the pressure compensation means are contained in a fluid-filled air-tight housing.

52. A device as claimed in any one of claims 47 to 51, wherein the pump means is an impeller adapted to drive fluid from the fluid reservoir and the aortic compression means.

53. A device as claimed in any one of claims 49 to 51, wherein the pump means is a fluid-filled sac adapted to be compressed to drive fluid from the sac to the aortic compression means.

54. A device as claimed in any one of claims 47 to 53, wherein the aortic compression means is an inflatable cuff adapted for positioning about the aorta of the patient.

55. A heart assist device adapted for implantation wholly into a bodily cavity of a patient, the device including:

c) an aortic compression means adapted, when actuated, to compress an aorta of a patient;

d) a housing with an exterior surface;

c) a fluid reservoir in the housing, the fluid reservoir having a flexible exterior surface forming part of the housing exterior surface; and

d) a pump means adapted to pump a fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means at least partly in counterpulsation with the patient's heart,

wherein the fluid reservoir flexible exterior surface is adapted to expand during aortic compression and constrict in the absence of aortic compression and is further adapted to be positioned substantially adjacent a flexible organ in the patient's bodily cavity.

56. A device as claimed in claim 55, wherein the bodily cavity is the thoracic cavity and the organ is the lung.

57. A heart assist device adapted for implantation into a patient, the device including:

a) an elastic inflatable cuff adapted, when inflated, to compress an aorta of a patient;

b) a fluid reservoir;

c) a means for pumping a fluid from the fluid reservoir to the cuff so as to inflate the aortic compression means at least partly in-counterpulsation with the patient's heart; and

d) a means for adjusting the volume of fluid in the cuff in the absence of aortic compression.

58. A device as claimed in claim 57, wherein the volume adjusting means is disposed between the cuff and the reservoir and is in fluid communication with the cuff and the reservoir.

59. A device as claimed in claim 57 or 58, wherein the volume adjusting means is a remote reservoir positioned near the patient's skin that is adapted for the receiving or the removal of fluid therein via a needle though the skin.

60. A device as claimed in claim 57 or 58, wherein the volume adjusting means is a remote reservoir positioned in the chest cavity that is adapted for the receiving or the removal of fluid therein via a transcutaneous tube connected thereto.

61. A human or animal having a heart assist device according to any one of the preceding claims implanted therein.

The demand must be filed directly with the competent International Preliminary Examining Authority or, if two or more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant on th eline below:

IPEA/_____

PCT

CHAPTER II

DEMAND

under Article 31 of the Patent Cooperation Treaty:
the undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty.

For International Preliminary Examining Authority use only

Identification of IPEA	Date of receipt of DEMAND

Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION

International application No.	International filing date *(day/month/year)*	Applicant's or agent's file reference / (Earliest) Priority date *(day/month/year)*
PCT/AU00/00654	9 June 2000 (09/06/00)	507717C 10 June 1999 (10/06/99)

Title of invention
HEART ASSIST DEVICES, SYSTEMS AND METHODS

Box No. II APPLICANT(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*
SUNSHINE HEART COMPANY PTY LTD
C/o 28D Montague Street
Balmain, New South Wales 2041
AUSTRALIA

Telephone No.:
Facsimile No.:
Teleprinter No.:

State *(i.e. country)* of nationality: Australia
State *(i.e. country)* of residence: Australia

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)*
PETERS, William Suttle
93 Bassett Road
Remuera
Auckland, 1005
NEW ZEALAND

State *(i.e. country)* of nationality: New Zealand
State *(i.e. country)* of residence: New Zealand

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)*
MARSH, Peter Crispin Lawrence
82 Louisa Road
Birchgrove, New South Wales 2041
AUSTRALIA

State *(i.e. country)* of nationality: Australia
State *(i.e. country)* of residence: Australia

☒ Further applicants are indicated on a continuation sheet.

Sheet No. 2

International application No.
PCT/AU00/00654

Continuation of Box No. II **APPLICANT(S)**

If none of the following sub-boxes is used, this sheet is not to be included in the demand

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)*

WHITE, Geoffrey Hamilton
22 Nicholson Street
East Balmain, New South Wales 2041
AUSTRALIA

State *(i.e. country)* of nationality:
Australia

State *(i.e. country)* of residence:
Australia

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)*

MILSOM, Frederick Paget
132 Long Drive
St Heliers
Auckland
NEW ZEALAND

State *(i.e. country)* of nationality:
New Zealand

State *(i.e. country)* of residence:
New Zealand

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)*

HENRICHSEN, Hans Hansforth
5 Smith Close
Shalvey, New South Wales 2770
AUSTRALIA

State *(i.e. country)* of nationality:
Australia

State *(i.e. country)* of residence:
Australia

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)*

UNGER, Rolf Gunnar
58A Caroline Street
Kingsgrove, New South Wales 2208
AUSTRALIA

State *(i.e. country)* of nationality:
Sweden

State *(i.e. country)* of residence:
Australia

[X] Further applicats are indicated on a continuation sheet.

International application No.
PCT/AU00/00654

Continuation of Box No. II **APPLICANT(S)**

If none of the following sub-boxes is used, this sheet is not to be included in the demand

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)*

SULLIVAN, Colin Edward
27 Wharf Road
Birchgrove, New South Wales 2041
AUSTRALIA

State *(i.e. country)* of nationality:	State *(i.e. country)* of residence:
Australia	Australia

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)*

State *(i.e. country)* of nationality:	State *(i.e. country)* of residence:

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)*

State *(i.e. country)* of nationality:	State *(i.e. country)* of residence:

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)*

State *(i.e. country)* of nationality:	State *(i.e. country)* of residence:

☐ Further applicats are indicated on a continuation sheet.

See Notes to the demand form

International application No.
PCT/AU00/00654

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The following person is [X] agent [ ] common representative

and [X] has been appointed earlier and represents the applicant(s) also for international preliminary examination.

[ ] is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.

[ ] is hereby appointed, specifically for the procedure before the International Preliminary Examing Authority, in addition to the agent(s)/common representative appointed earlier.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

Spruson & Ferguson
GPO Box 3898
Sydney, New South Wales 2001
AUSTRALIA

Telephone No. :
(02) 9207 0777

Facsimile No. :
(02) 9232 8555

Teleprinter No. :
AA 23165

[ ] Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. IV STATEMENT CONCERNING AMENDMENTS

The applicant wishes the International Preliminary Examining Authority*

(i) [X] to start the international preliminary examination on the basis of the international application as originally filed.

(ii) [ ] to take into account the amendments under Article 34 of

- [ ] the description (amendments attached).
- [ ] the claims (amendments attached).
- [ ] the drawings (amendments attached).

(iii) [ ] to take into account any amendments of the claims under Article 19 filed with the International Bureau (a copy is attached).

(iv) [ ] to disregard any amendments of the claims made under Article 19 and to consider them as reversed.

(v) [ ] to postpone the start of the international preliminary examination until the expiration of 20 months from the priority date unless that Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69.1(d)). *(This check-box may be marked only where the time limit under Article 19 has not yet expired.)*

* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Box No. V ELECTION OF STATES

[X] The applicant hereby elects all eligible States *(that is, all States which have been designated and which are bound by Chapter II of the PCT)* except

(If the applicant does not wish to elect certain eligible States, the name(s) or country codes(s) of those States must be indicated above)

International application No.
PCT/AU00/00654

Box No. VI CHECK LIST

The demand is accompanied by the following documents for the purposes of international preliminary examination:			For International Preliminary Examining Authority use only: Received	not received
1. amendments under Article 34				
Description	:	sheets	☐	☐
Claims	:	sheets	☐	☐
Drawings	:	sheets	☐	☐
2. letter accompanying amendments under Article 34	:	sheets	☐	☐
3. copy of amendments under Article 19	:	sheets	☐	☐
4. copy of statement under Article 19	:	sheets	☐	☐
5. other *(specify)*	:	sheets	☐	☐

The demand is also accompanied by the item(s) marked below:

1. ☐ separate signed power of attorney
2. ☐ copy of general power of attorney
3. ☐ statement explaining lack of signature
4. ☒ fee calculation sheet
5. ☐ other *(specify)*:

Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).

Greg Turner
Registered Patent Attorney
SPRUSON & FERGUSON

For International Preliminary Examining Authority use only

1.		Date of actual receipt of DEMAND	
2.		Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):	
3.	☐	The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 and 5, below, does not apply.	☐ The applicant has been informed accordingly.
4.	☐	The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5.	
5.	☐	Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.	

For International Bureau use only

Demand received from IPEA on:

See Notes to the demand form

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* 507717C

Box No. I TITLE OF INVENTION

HEART ASSIST DEVICES, SYSTEMS AND METHODS

Box No. II APPLICANT

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (i.e. country) of residence if no State of residence is indicated below.)*

SUNSHINE HEART COMPANY PTY LTD
c/o 28D Montague Street
Balmain New South Wales 2041
AUSTRALIA

☐ This person is also inventor

Telephone No.

Facsimile No.

Teleprinter No.

State *(i.e. country)* of nationality: Australia

State *(i.e. country)* of residence: Australia

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (i.e. country) of residence if no State of residence is indicated below.)*

PETERS, William Suttle
93 Bassett Road
Remuera
Auckland, 1005
NEW ZEALAND

This person is :

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(i.e. country)* of nationality: New Zealand

State *(i.e. country)* of residence: New Zealand

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as : ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)*

SPRUSON & FERGUSON
GPO BOX 3898
Sydney
New South Wales 2001
AUSTRALIA

Telephone No.
(02) 9207 0777

Facsimile No.
(02) 9232 8555

Teleprinter No.
AA 23165

☐ Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III **FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)**

If none of the following sub-boxes is used, this sheet is not to be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (i.e. country) of residence if no State of residence is indicated below.)*

MARSH, Peter Crispin Lawrence
82 Louisa Road
Birchgrove, New South Wales, 2041
AUSTRALIA

This person is :
☐ applicant only
☒ applicant and inventor
☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(i.e. country)* of nationality: Australia

State *(i.e. country)* of residence: Australia

This person is applicant for the purposes of : ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ The States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)*

WHITE, Geoffrey Hamilton
22 Nicholson Street
East Balmain, New South Wales, 2041
AUSTRALIA

This person is
☐ applicant only
☒ applicant and inventor
☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(i.e. country)* of nationality: Australia

State *(i.e. country)* of residence: Australia

This person is applicant for the purposes of : ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ The States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)*

MILSOM, Frederick Paget
132 Long Drive
St Heliers
Auckland
NEW ZEALAND

This person is :
☐ applicant only
☒ applicant and inventor
☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(i.e. country)* of nationality: New Zealand

State *(i.e. country)* of residence: New Zealand

This person is applicant for the purposes of : ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ The States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)*

HENRICHSEN, Hans Hansforth
5 Smith Close
Shalvey, New South Wales, 2770
AUSTRALIA

This person is :
☐ applicant only
☒ applicant and inventor
☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(i.e. country)* of nationality: Australia

State *(i.e. country)* of residence: Australia

This person is applicant for the purposes of : ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ The States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a contiuation sheet.

Continuation of Box No. III **FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)**

If none of the following sub-boxes is used, this sheet is not to be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (i.e. country) of residence if no State of residence is indicated below.)*

UNGER, Rolf Gunnar
58A Caroline Street
Kingsgrove, New South Wales, 2208
AUSTRALIA

This person is :
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked do not fill in below)*

State *(i.e. country)* of nationality: Sweden

State *(i.e. country)* of residence: Australia

This person is applicant for the purposes of : ☐ all designated States ☐ all designated States except the United states of America ☒ the United states of America only ☐ The States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)*

SULLIVAN, Colin Edward
27 Wharf Road
Birchgrove, New South Wales, 2041
AUSTRALIA

This person is :
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked do not fill in below)*

State *(i.e. country)* of nationality: Australia

State *(i.e. country)* of residence: Australia

This person is applicant for the purposes of : ☐ all designated States ☐ all designated States except the United states of America ☒ the United states of America only ☐ The States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)*

This person is :
- ☐ applicant only
- ☐ applicant and inventor
- ☐ inventor only *(If this check-box is marked do not fill in below)*

State *(i.e. country)* of nationality:

State *(i.e. country)* of residence:

This person is applicant for the purposes of : ☐ all designated States ☐ all designated States except the United states of America ☐ the United states of America only ☐ The States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)*

This person is :
- ☐ applicant only
- ☐ applicant and inventor
- ☐ inventor only *(If this check-box is marked do not fill in below)*

State *(i.e. country)* of nationality:

State *(i.e. country)* of residence:

This person is applicant for the purposes of : ☐ all designated States ☐ all designated States except the United states of America ☐ the United states of America only ☐ The States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) *(mark the applicable check-boxes; at least one must be marked)*:

Regional Patent

- ☒ AP **ARIPO Patent:** GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SL Sierra Leone, SZ Swaziland, TZ United Republic of Tanzania, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ EA **Eurasian Patent:** AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Tukmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ EP **European Patent:** AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden , and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ OA **OAPI Patent:** BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)*.....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

☒	AE	United Arab Emirates	☒	LR	Liberia
☒	AL	Albania	☒	LS	Lesotho
☒	AM	Armenia	☒	LT	Lithuania
☒	AT	Austria	☒	LU	Luxembourg
☒	AU	Australia	☒	LV	Latvia
☒	AZ	Azerbaijan	☒	MA	Morocco
☒	BA	Bosnia and Herzegovina	☒	MD	Republic of Moldova
☒	BB	Barbados	☒	MG	Madagascar
☒	BG	Bulgaria	☒	MK	The former Yugoslav Republic of Macedonia
☒	BR	Brazil			
☒	BY	Belarus	☒	MN	Mongolia
☒	CA	Canada	☒	MW	Malawi
☒	CH and LI	Switzerland and Liechtenstein	☒	MX	Mexico
☒	CN	China	☒	NO	Norway
☒	CR	Costa Rica	☒	NZ	New Zealand
☒	CU	Cuba	☒	PL	Poland
☒	CZ	Czech Republic	☒	PT	Portugal
☒	DE	Germany	☒	RO	Romania
☒	DK	Denmark	☒	RU	Russian Federation
☒	DM	Dominica	☒	SD	Sudan
☒	EE	Estonia	☒	SE	Sweden
☒	ES	Spain	☒	SG	Singapore
☒	FI	Finland	☒	SI	Slovenia
☒	GB	United Kingdom	☒	SK	Slovakia
☒	GD	Grenada	☒	SL	Sierra Leone
☒	GE	Georgia	☒	TJ	Tajikistan
☒	GH	Ghana	☒	TM	Turkmenistan
☒	GM	Gambia	☒	TR	Turkey
☒	HR	Croatia	☒	TT	Trinidad and Tobago
☒	HU	Hungary	☒	TZ	United Republic of Tanzania
☒	ID	Indonesia	☒	UA	Ukraine
☒	IL	Israel	☒	UG	Uganda
☒	IN	India	☒	US	United States of America
☒	IS	Iceland			
☒	JP	Japan	☒	UZ	Uzbekistan
☒	KE	Kenya	☒	VN	Viet Nam
☒	KG	Kyrgyzstan	☒	YU	Yugoslavia
☒	KP	Democratic People's Republic of Korea	☒	ZA	South Africa
			☒	ZW	Zimbabwe
☒	KR	Republic of Korea	Check-boxes reserved for designating States which have become party to the PCT after issuance of this sheet:		
☒	KZ	Kazakhstan			
☒	LC	Saint Lucia	☒	DZ	Algeria
☒	LK	Sri Lanka	☒	AG	Antigua & Barbuda
			☒	MZ	Mozambique

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except the designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)*

Box No. VI PRIORITY CLAIM Further priority claims are indicated in the Supplemental Box ☐

The priority of the following earlier application(s) is hereby claimed:

Country *(in which, or for which, the application was filed)*	Filing Date *(day/month/year)*	Application No.	Office of filing *(only for regional or international application)*
item (1) AUSTRALIA	(10.06.99) 10 June 1999	PQ0904	
item (2)			
item (3)			

Mark the following check-box if the certified copy of the earlier application is to be issued by the Office which for the purposes of the present international application is the receiving Office (a fee may be required):

☒ The receiving Office is hereby requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): (1)

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(If two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):* ISA/_____

Earlier search *Fill in where a search (international, international-type or other) by the International Searching Authority has already been carried out or requested and the Authority is now requested to base the international search, to the extent possible, on the results of that earlier search. Identify such search or request either by reference to the relevant application (or the translation thereof) or by reference to the search request:*

Country (or regional Office): Date *(day/month/year)* Number:

Box No. VIII CHECK LIST

This international application contains the following number of sheets:

1. request	:	5 sheets
2. description	:	16 sheets
3. claims	:	6 sheets
4. abstract	:	1 sheets
5. drawings	:	10 sheets
Total	:	38 sheets

This international application is accompanied by the item(s) marked below:

1. ☐ separate signed power of attorney
2. ☐ copy of general power of attorney
3. ☐ statement explaining lack of signature
4. ☐ priority document(s) *identified in Box No. VI as item(s):*
5. ☒ fee calculation sheet
6. ☐ separate indications concerning deposited microorganisms
7. ☐ nucleotide and/or amino acid sequence listing (diskette)
8. ☐ other *(specify):*

Figure No. of the drawings (if any) should accompany the abstract when it is published.

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

Ryan Durrick
Registered Patent Attorney
SPRUSON & FERGUSON

For receiving Office use only

1. Date of actual receipt of the purported international application:
2. Drawings ☐ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:
4. Date of timely receipt of the required corrections under PCT Article 11(2):
5. International Searching Authority specified by the applicant: ISA/
6. ☐ Transmittal of search copy delayed until search fee is paid

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 19 February 2001 (19.02.01)	
International application No. PCT/AU00/00654	**Applicant's or agent's file reference** 507717C
International filing date (day/month/year) 09 June 2000 (09.06.00)	**Priority date** (day/month/year) 10 June 1999 (10.06.99)
Applicant PETERS, William, Suttle et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

28 December 2000 (28.12.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer F. Baechler
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

Copy for the designated Office (DO/US) PCT/AU00/00654

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

SPRUSON & FERGUSON
GPO Box 3898
Sydney, NSW 2001
AUSTRALIE

Date of mailing (day/month/year)
26 January 2001 (26.01.01)

Applicant's or agent's file reference
507717C

IMPORTANT NOTIFICATION

International application No.
PCT/AU00/00654

International filing date (day/month/year)
09 June 2000 (09.06.00)

1. The following indications appeared on record concerning:

[X] the applicant [X] the inventor [ ] the agent [ ] the common representative

Name and Address
UNGER, Rolf, Gunnar
58A Caroline Street
Kingsgrove, NSW 2208
Australia

State of Nationality: AU
State of Residence: AU
Telephone No.:
Facsimile No.:
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [ ] the name [ ] the address [X] the nationality [ ] the residence

Name and Address
UNGER, Rolf, Gunnar
58A Caroline Street
Kingsgrove, NSW 2208
Australia

State of Nationality: SE
State of Residence: AU
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[ ] the International Preliminary Examining Authority
[X] the designated Offices concerned
[ ] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer
Athina Nickitas-Etienne

Telephone No.: (41-22) 338.83.38